IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MARK ELFERS, Derivatively On Behalf Of Nominal Defendant ABBVIE, INC.,	)	
Plaintiff,	)	C.A No.: 20-CV-00213-MN
v.	)	
RICHARD A. GONZALEZ, ROXANNE S. AUSTIN, ROBERT J. ALPERN, EDWARD M. LIDDY, EDWARD J. RAPP, MELODY B. MEYER, GLENN F. TILTON, FREDERICK H. WADDELL, WILLIAM H.L. BURNSIDE, BRETT J. HART and WILLIAM J. CHASE,	)	
Defendants,	)	**JURY TRIAL DEMANDED**
ABBVIE, INC., a Delaware Corporation,	)	
Nominal Defendant.	)	

VERIFIED AMENDED SHAREHOLDER DERIVATIVE COMPLAINT

Plaintiff Mark Elfers ("Plaintiff"), by and through his undersigned counsel, derivatively on behalf of Nominal Defendant AbbVie, Inc. ("AbbVie" or the "Company"), submits this Verified Amended Shareholder Derivative Complaint (the "Complaint"). Plaintiff's allegations are based upon his personal knowledge as to himself and his own acts, and upon information and belief, developed from the investigation and analysis by Plaintiff's counsel, including a review of publicly available information, including filings by AbbVie with the U.S. Securities and Exchange Commission ("SEC"), press releases, news reports, analyst reports, investor conference transcripts, publicly available filings in lawsuits, and matters of public record.

NATURE OF THE ACTION

1. This is a federal securities fraud action and a shareholder derivative action brought on behalf of and for the benefit of AbbVie, against certain of its officers and/or directors named as

defendants herein seeking to remedy their breaches of fiduciary duties and other wrongful conduct as alleged herein. Defendants' actions have caused, and will continue to cause, substantial financial harm and other damages to AbbVie, including damages to its reputation and goodwill.

JURISDICTION AND VENUE

2. Pursuant to 28 U.S.C. § 1331, 15 U.S.C. § 78aa and Section 27 of the Securities Exchange Act of 1934 (the "Exchange Act"), this Court has exclusive jurisdiction over the claims asserted herein for violations of Sections 10(b) and 14(a) of the Exchange Act and SEC Rule 14a-9 promulgated thereunder. This Court has supplemental jurisdiction over the remaining claims under 28 U.S.C. § 1367.

3. The district courts of the United States and the United States courts of any Territory or other place subject to the jurisdiction of the United States shall have exclusive jurisdiction of violations of this title [15 USCS §§ 78a *et seq.*] or the rules and regulations thereunder, and of all suits in equity and actions at law brought to enforce any liability or duty created by this title [15 USCS §§ 78a *et seq*.] or the rules and regulations thereunder.

4. This Court has jurisdiction over each defendant named herein because each defendant is either a corporation that conducts business in and maintains operations in this District or is an individual who has sufficient minimum contacts with this District to render the exercise of jurisdiction by the District courts permissible under traditional notions of fair play and substantial justice.

5. Venue is proper in this Court in accordance with 28 U.S.C. § 1391 because AbbVie is incorporated in this District. *See* 28 U.S.C. § 1332(c)(1) ("[A] corporation shall be deemed to be a citizen of every State and foreign state by which it has been incorporated and of the State or foreign state where it has its principal place of business."). AbbVie is incorporated in Delaware and its principal place of business is located at 1 North Waukegan Road, North Chicago, IL 60064.

6. Venue is also proper in this Court because a substantial portion of the transactions and wrongs complained of herein, including Defendants' primary participation in the wrongful acts

detailed herein, and aiding and abetting and conspiracy in violation of fiduciary duties owed to AbbVie, occurred in this District.

7. In addition, the Company's DEF 14A, filed with the SEC on March 23, 2020 states in relevant part: "AbbVie is incorporated in the state of Delaware and Delaware law governs the relationship among its directors, officers, and stockholders (also known as the internal affairs doctrine). To provide for the orderly, efficient and cost-effective resolution of Delaware-law issues affecting AbbVie, the company's Certificate of Incorporation provides that unless the board of directors otherwise determines, ***Delaware courts*** are the exclusive forum for cases involving the internal affairs doctrine, derivative actions brought on behalf of the company, claims for breach of fiduciary duty, and other matters concerning Delaware statutory and common law. The provision does not apply to any other cases brought against AbbVie." (Emphasis added). This United States District Court for the District of Delaware is such a court.

PARTIES

Plaintiff

8. ***Plaintiff Mark Elfers*** is a current AbbVie shareholder and has been one during the relevant period at issue. Plaintiff will continue to hold AbbVie shares throughout the pendency of this action. Plaintiff will fairly and adequately represent the interests of the shareholders in enforcing the rights of the corporation.

Nominal Defendant

9. Nominal Defendant AbbVie is a Delaware corporation. Nominal Defendant AbbVie is a citizen of the states of Delaware and Illinois.

Director Defendants

10. ***Defendant Richard A. Gonzalez*** ("Gonzalez") has served as the Company's Chief Executive Officer ("CEO") and Chairman of the Board of Directors ("Board") since December 2012. Defendant Gonzalez owns 279,337 shares of the Company's stock, which is roughly $31.3 million worth of AbbVie stock.

11. Defendant Gonzalez served as Abbott Laboratories, Inc. ("Abbott")[1] Executive Vice President of the pharmaceutical products group from July 2010 to December 2012, and was responsible for Abbott's worldwide pharmaceutical business, including commercial operations, research and development, and manufacturing. He also served as president, Abbott Ventures Inc., Abbott's medical technology investment arm, from 2009 to 2011. Defendant Gonzalez joined Abbott in 1977 and held various management positions before briefly retiring in 2007, including: Abbott's President and Chief Operating Officer; President, Chief Operating Officer of Abbott's Medical Products Group; Senior Vice President and President of Abbott's former Hospital Products Division; Vice President and President of Abbott's Health Systems Division; and divisional Vice President and General Manager for Abbott's Diagnostics Operations in the United States and Canada.

12. For year ended December 31, 2017, Defendant Gonzalez received $22,625,243 in compensation from the Company, which included $1,638,462 in salary, $9,606,360 in stock awards, $2,559,270 in option awards, $4,331,250 in non-equity incentive plan compensation, $3,496,704 in change in pension value and non-qualified deferred compensation earnings, and $993,197 in all other compensation.

13. At the time the Company was issuing false and misleading information to the market, Defendant Gonzalez sold the following Company stock:

Date	***Shares***	***Price***	***Proceeds***
02/28/18	8,280	$117.89	$976,129.20
11/21/17	218,193	$94.01	$218,287.01
08/07/17	193,131	$71.03	$13,718,094.00
08/04/17	22,038	$71.08	$1,566,461.00
08/03/17	65,861	$71.00	$4,676, 131.00
05/19/17	71,235	$65.48	$4,664,467.80
03/08/17	72,016	$64.25	$4,627,028.00

[1] On January 1, 2013, AbbVie became an independent, publicly-traded company as a result of the distribution by Abbott Laboratories Inc. of 100% of the outstanding common stock of AbbVie to Abbott's shareholders.

Date	*Shares*	*Price*	*Proceeds*
06/02/16	285,953	$63.87	$18,263,818.00
05/11/16	39,000	$63.80	$2,488,200.00
07/29/15	40,021	$71.25	$2,851,496.20
07/29/15	24,979	$71.09	$1,775,757.10
04/28/15	62,932	$64.87	$4,079,881.50
04/28/15	8,281	$64.93	$537,685.33
04/08/15	1,300	$64.87	$84,331.00
04/04/14	4,799	$51.20	$245,708.80

14. Defendant Gonzalez sold 1,118,019 shares of Company stock with knowledge of material non-public information.

15. ***Defendant Roxanne S. Austin*** ("Austin") has served as a Company director since 2013. Defendant Austin also serves as Chairperson of the Audit Committee and a member of the Compensation Committee. Defendant Austin owns 36,296 shares of the Company's common stock, which is roughly $4 million worth of AbbVie stock.

16. For the year ended December 31, 2017, Defendant Austin received $320,300 in compensation from the Company, which included $130,000 in fees earned or paid in cash, $184,981 in restricted stock unit awards, and $5,319 in all other compensation.

17. ***Defendant Robert J. Alpern*** ("Alpern") has served as a Company director since 2013. Defendant Alpern also serves as a member of the Nominations and Governance Committee and the Public Policy Committee. Defendant Alpern owns 21,789 shares of the Company's common stock, which is roughly $2.4 million worth of AbbVie stock.

18. For the year ended December 31, 2017, Defendant Alpern received $335,929 in compensation from the Company, which includes $105,000 in fees earned or paid in cash, $184,981 in restricted stock unit awards, $20,948 in change in pension value and nonqualified deferred compensation earnings, and $25,000 in all other compensation.

19. ***Defendant Edward M. Liddy*** ("Liddy") has served as a Company director since 2013. Defendant Liddy also serves as Chairperson of the Compensation Committee and as a

member of the Public Policy Committee. Defendant Liddy owns 18,351 shares of the Company's common stock, which is roughly $2 million worth of AbbVie stock.

20. For the year ended December 31, 2017, Defendant Liddy received $309,981 in compensation from the Company, which included $125,000 in fees earned or paid in cash and $184,981 in restricted stock unit awards.

21. ***Defendant Edward J. Rapp*** ("Rapp") has served as a Company director since 2013. Defendant Rapp also serves as Chairperson of the Public Policy Committee and as a member of the Audit Committee. Defendant Rapp owns 15,498 shares of the Company's common stock, which is roughly $1.7 million worth of AbbVie stock.

22. For the year ended December 31, 2017, Defendant Rapp received $342,025 in compensation from the Company, which included $131,000 in fees earned or paid in cash, $184,981 in restricted stock unit awards, and $26,044 in all other compensation.

23. ***Defendant Melody B. Meyer*** ("Meyer") has served as a Company director since May 2017. Defendant Meyer also serves as a member of the Audit Committee and the Public Policy Committee. Defendant Meyer owns 2,770 shares of the Company's common stock, which is roughly $310,849 worth of AbbVie stock.

24. For the year ended December 31, 2017, Defendant Meyer received $274,731 in compensation from the Company, which included $64,750 in fees earned or paid in cash, $184,981 in restricted stock unit awards, and $25,000 in all other compensation.

25. ***Defendant Glenn F. Tilton*** ("Tilton") has served as a Company director since 2013. Defendant Tilton also serves as Lead Director, Chairperson of the Nominations and Governance Committee, and as a member of the Compensation Committee. Defendant Tilton owns 32,786 shares of the Company's common stock, which is roughly $3.6 million worth of AbbVie stock.

26. For the year ended December 31, 2017, Defendant Tilton received $359,981 in compensation from the Company, which included $150,000 in fees earned or paid in cash, $184,981 in restricted stock unit awards, and $25,000 in all other compensation.

27. ***Defendant Frederick H. Waddell*** ("Waddell") has served as a Company director since 2013. Defendant Waddell also serves as a member of the Audit Committee and the Compensation Committee. Defendant Waddell owns 15,230 shares of the Company's common stock, which is roughly $1.7 million worth of AbbVie stock.

28. For the year ended December 31, 2017, Defendant Waddell received $320,981 in compensation from the Company, which included $111,000 in fees earned or paid in cash, $184,981 in restricted stock unit awards, and $25,000 in all other compensation.

29. ***Defendant William H.L. Burnside*** ("Burnside") has served as a Company director since 2013. Defendant Burnside also serves as a member of the Audit Committee and Nominations and Governance Committee. Defendant Burnside owns 13,230 shares of the Company's common stock, which is roughly $1.4 million worth of AbbVie stock.

30. For the year ended December 31, 2017, Defendant Burnside received $320,981 in compensation from the Company, which included $111,000 in fees earned or paid in cash, $184,981 in restricted stock unit awards, and $25,000 in all other compensation.

31. ***Defendant Brett J. Hart*** ("Hart") has served as a Company director since 2016. Defendant Hart also serves as a member of the Nominations and Governance Committee. Defendant Hart owns 5,744 shares of the Company's common stock, which is roughly $644,591 worth of AbbVie stock.

32. For the year ended December 31, 2017, Defendant Hart received $314,981 in compensation from the Company, which included $105,000 in fees earned or paid in cash, $184,981 in restricted stock unit awards, and $25,000 in all other compensation.

33. Defendants Gonzalez, Austin, Alpern, Liddy, Rapp, Meyer, Tilton, Wadell, Burnside and Hart are collectively referred to herein as the "Director Defendants".

Officer Defendant

34. ***Defendant William J. Chase*** ("Chase") has served as the Company's Executive Vice President, Finance and Administration since October 19, 2018, and also served as the

Company's Executive Vice President, Chief Financial Officer ("CFO") from December 2012 until October 19, 2018. Defendant Chase served as Abbott Laboratories Inc.'s ("Abbott") Vice President, Licensing and Acquisitions from 2010 to 2012, as Vice President, Treasurer from 2007 to 2010, and as Divisional Vice President, Controller of Abbott International from 2004 to 2007. Chase joined Abbott in 1989

35. Defendant Chase owns 184,044 shares of the Company's stock, which is roughly $20.6 million worth of AbbVie stock.

36. For the year ended December 31, 2017, Defendant Chase received $12,044,593 in compensation from the Company, which included $1,008,526 in salary, $3,681,906 in stock awards, $980,980 in option awards, $1,954,549 in non-equity incentive plan compensation, $4,223,300 in change in pension value and non-qualified deferred compensation earnings, and $195,332 in all other compensation.

37. At the time the Company was issuing false and misleading information to the market, Defendant Chased sold the following Company stock:

Date	***Shares***	***Price***	***Proceeds***
02/28/18	38,528	$119.44	$4,601,784.30
03/01/18	32,400	$114.5	$3,709,800.00
05/18/17	38,300	$65.35	$2,502,905.00
12/02/16	6,600	$59.19	$390,654.00
12/22/14	8,495	$68.00	$577,660.00
03/03/14	3,948	$50.53	$199,492.44

38. Defendant Chase sold 128,271 shares of Company stock (for which he received over $11.9 million) with knowledge of material non-public information.

39. Defendant Chase, along with the Directors Defendants, are collectively referred to herein as "Defendants".

Non-Party

40. ***Non-Party Rebecca B. Roberts*** ("Roberts") is a director of the Company.

CORPORATE GOVERNANCE

41. As members of AbbVie's Board, the Director Defendants were held to the highest standards of honesty and integrity and charged with overseeing the Company's business practices and policies and assuring the integrity of its financial and business records.

THE COMPANY'S CODE OF BUSINESS CONDUCT

42. The Company has a Code of Business Conduct Handbook. It states in relevant part:

> WE MAKE GOOD DECISIONS OUR CODE CANNOT TELL YOU WHAT TO DO IN EVERY SITUATION.
>
> In most circumstances, if you abide by our policies and procedures and the law, your decision is probably the right one. Use your best judgment. Be honest and fair. If the right choice is not clear, consult your manager, the Office of Ethics and Compliance, our Legal Department or another one of our Contacts.
>
> * * *
>
> WE INTERACT HONESTLY WITH HEALTHCARE PROVIDERS HEALTHCARE PROVIDERS ARE AT THE FRONT LINES OF DISEASE MANAGEMENT.
>
> We collaborate to ensure our products are appropriately prescribed and distributed to the patients who need them. Our dedication to clear communications with healthcare providers serves the best interests of patients and supports medical advancements.
>
> We take care to ensure product information is accurate, comprehensive, relevant and up to date. We are fair and open in our dealings with healthcare providers and customers. We do not offer or give gifts or other items or services of value as a means to earn favor for our products or to sway medical judgment. We rely on product quality and healthcare outcomes to influence purchasing and prescribing practices. This reinforces the positive reputation we have earned worldwide.
>
> * * *
>
> WE FOLLOW INDUSTRY LAWS AND REGULATIONS
>
> WE VALUE THE LONG-STANDING TRUST WE HAVE EARNED WORLDWIDE.
>
> Patients, healthcare providers, customers and suppliers know they can rely on us because we comply with the laws, regulations and codes that govern the pharmaceutical industry and our company (e.g., European Federation of Pharmaceutical Industries and Associations [EFPIA] and International Federation of

Pharmaceutical Manufacturers and Associations [IFPMA]).

* * *

WE MAINTAIN TRUSTWORTHY BUSINESS PRACTICES

WE COMPLY WITH ALL APPLICABLE LAWS THAT REGULATE OUR BUSINESS.

Many of these laws concern the way we promote and sell our medical products. It is never acceptable to try to influence purchasing decisions in any way that is unethical, inappropriate or illegal or creates a potential conflict of interest.

We are honest, open and up-front when we interact with those who may be interested in buying or prescribing our products.

* * *

WE COMPLY WITH ANTI-BRIBERY AND ANTI-CORRUPTION LAWS

WE DO NOT TOLERATE IMPROPER PAYMENTS. WE UNDERSTAND THAT ACCEPTING, OFFERING OR GIVING ANYTHING OF VALUE TO INFLUENCE

A BUSINESS DECISION OR GAIN AN UNFAIR BUSINESS ADVANTAGE IS IMPROPER.

We also understand that improper payments received or given can have severe repercussions for the individuals involved, for AbbVie and ultimately, for our industry and the people we serve. We are careful to maintain accurate books and records to reflect all payments made and received, and we avoid even the appearance of anything improper.

We recognize that we may be responsible for improper payments made by third parties conducting business on our behalf, so we have due diligence processes in place to ensure we know who we are working with, that they have a reputation for operating honestly and with integrity and that any payments made on our behalf are appropriate.

Although common in some countries, we prohibit “facilitation” payments to public officials for taking routine governmental actions.

* * *

WE COMPLY WITH INSIDER TRADING LAWS

IN THE COURSE OF OUR JOBS, WE MAY HEAR OR KNOW ABOUT A

COMPANY'S BUSINESS ACTIVITIES OR PLANS THAT ARE NOT YET PUBLICIZED.

Information that has not been made public, but if known, may persuade a reasonable investor to buy, sell or hold a company's securities is called "inside" or "nonpublic" information. Never use this information – whether it is about AbbVie or any other company -- to conduct a trade. Never "tip" someone else on what you know so that they may trade. Insider trading and tipping are illegal.

* * *

WE ARE ALERT FOR PAYMENTS FROM SUSPICIOUS SOURCES

PURCHASES AND PAYMENTS MADE IN UNUSUAL WAYS MAY SIGNAL ILLEGAL ACTIVITY.

Watch out for payments made to AbbVie or on our behalf that come from an unknown source, are all-cash payments or are payments made through a personal bank account or financial institution with no relation to the customer or business partner. Report any such transaction that you feel is suspicious to our Legal Department or Finance Department.

AUDIT COMMITTEE CHARTER

43. The Audit Committee shall assist the Board in fulfilling its oversight responsibility with respect to:

- AbbVie's accounting and financial reporting practices and the audit process
- the quality and integrity of AbbVie's financial statements;
- the independent auditors' qualifications, independence, and performance;
- the performance of AbbVie's internal audit function and internal auditors;
- legal and regulatory compliance as it relates to financial matters, including accounting, auditing, financial reporting, and securities law issues (recognizing that other board committees assist the Board in reviewing other areas of legal and regulatory compliance); and
- AbbVie's enterprise risk management, including major financial risk exposures (recognizing that other board committees assist the Board in reviewing certain aspects of risk management);

and shall prepare the report required by the rules of the Securities and Exchange Commission to be included in AbbVie's annual proxy statement.

***

The Audit Committee shall:

- Prepare the report required by the rules of the Securities and Exchange Commission to be included in AbbVie's annual proxy statement.

- Meet separately, periodically, with AbbVie's independent auditors, with AbbVie's management and with AbbVie's internal auditors.

- At least annually, evaluate the qualifications, performance, and independence of AbbVie's independent auditors and appoint a firm of independent public accountants to act as AbbVie's independent auditors. This evaluation shall include the review and evaluation of the lead partner of AbbVie's independent auditors and shall take into account the opinions of AbbVie's management and internal auditors. In connection with this evaluation and appointment, the Audit Committee shall obtain and review a report by AbbVie's then current independent auditors describing:

  - the independent auditors' internal quality-control procedures;
  - any material issues raised by the most recent internal quality-control review, or peer review, of the independent auditors, or by any inquiry or investigation by governmental or professional authorities, within the preceding five years, respecting one or more independent audits carried out by the independent auditors, and any steps taken to deal with any such issues; and
  - all relationships between the independent auditors and AbbVie. [*See* Exhibit A attached hereto for Audit Committee Charter].

DUTIES OF THE DIRECTOR DEFENDANTS

44. By reason of their positions as officers, directors, and/or fiduciaries of AbbVie and because of their ability to control the business and corporate affairs of AbbVie, the Director Defendants owed the Company and its shareholders fiduciary obligations of trust, loyalty, good faith and due care, and were and are required to use their utmost ability to control and manage AbbVie in a fair, just, honest, and equitable manner. The Director Defendants were and are required to act in furtherance of the best interests of AbbVie and its shareholders so as to benefit all shareholders equally, and not in furtherance of their personal interest or benefit.

45. Each director and officer of the Company owes to AbbVie and its shareholders the fiduciary duty to exercise good faith and diligence in the administration of the affairs of the Company and in the use and preservation of its property and assets, as well as the highest obligations of fair dealing. In addition, as officers and/or directors of a publicly held company, the Director

Defendants had a duty to promptly disseminate accurate and truthful information with regard to the Company's operations, finances, financial condition, and present and future business prospects so that the market price of the Company's stock would be based on truthful and accurate information.

46. The Director Defendants, because of their positions of control and authority as directors and/or officers of AbbVie, were able to and did, directly and/or indirectly, exercise control over the wrongful acts complained of herein, as well as the contents of the various public statements issued by the Company. Because of their advisory, executive, managerial and directorial positions with AbbVie, each of the Defendants had access to adverse non-public information about the financial condition, operations, sales and marketing practices, and improper representations of AbbVie.

47. To discharge their duties, the officers and directors of AbbVie were required to exercise reasonable and prudent supervision over the management, policies, practices, and controls of the financial affairs of the Company. By virtue of such duties, the officers and directors of AbbVie were required to, among other things:

(a) ensure that the Company complied with its legal obligations and requirements, including acting only within the scope of its legal authority and disseminating truthful and accurate statements to the investing public;

(b) conduct the affairs of the Company in an efficient, business-like manner so as to make it possible to provide the highest quality performance of its business, to avoid wasting the Company's assets, and to maximize the value of the Company's stock;

(c) properly and accurately guide investors and analysts as to the true financial condition of the Company at any given time, including making accurate statements about the Company's business prospects, and ensuring that the Company maintained an adequate system of financial controls such that the Company's financial reporting would be true and accurate at all times;

(d) remain informed as to how AbbVie conducted its operations, and, upon receipt of notice or information of imprudent or unsound conditions or practices, make reasonable inquiry in connection therewith, take steps to correct such conditions or practices and make such disclosures as necessary to comply with federal and state securities laws; and

(e) ensure that the Company was operated in a diligent, honest and prudent manner in compliance with all applicable federal, state and local laws, rules and regulations.

48. Each Director Defendant, by virtue of his position as a director and/or officer, owed to the Company and to its shareholders the fiduciary duties of loyalty, good faith, and the exercise of due care and diligence in the management and administration of the affairs of the Company, as well as in the use and preservation of its property and assets. The conduct of the Director Defendants complained of herein involves a knowing and culpable violation of their obligations as directors and officers of AbbVie, the absence of good faith on their part, and a reckless disregard for their duties to the Company and its shareholders that the Director Defendants were aware or should have been aware posed a risk of serious injury to the Company.

49. In addition, as officers and/or directors of a publicly held company, Defendants had a duty not to advance their own personal, financial, or economic interests over, and at the expense of, the Company's public shareholders, or to allow other AbbVie directors, officers, and/or employees to do so. Each director and officer of the Company also owed AbbVie and its shareholder-owners the duty to maintain the Company's confidential information and prevent others from misappropriating and/or trading while in possession of the Company's proprietary, confidential information.

50. The Director Defendants breached their duties of loyalty and good faith by causing the Company to misrepresent the information as detailed *infra*. The Director Defendants' subjected the Company to the costs of defending, and the potential liability from, the securities class action

(and related lawsuits). As a result, AbbVie has expended, and will continue to expend, significant sums of money.

51. The Director Defendants' actions have irreparably damaged AbbVie's corporate image and goodwill.

COMPANY BACKGROUND AND INFORMATION

The Company's Operations

52. The Company is a global, research-based biopharmaceutical company that discovers, develops, manufactures, and sells pharmaceutical products in the United States and internationally. The Company was officially formed on January 1, 2013, following the split of Abbott into two publicly traded companies. The "new" Abbott would specialize in diversified products including medical devices, diagnostic equipment, and nutrition products, while AbbVie would operate as a research-based pharmaceutical manufacturer.

53. Shortly after the Company was spun off, on June 13, 2013, Defendant Chase stated: "[W]hat's beautiful about this business ***is its relatively simple business model***, right. At the end of the day, ***it's about making sure we achieve everything we can with Humira, which has tremendous growth potential***."

Humira Was (and Is) Critically Important to the Company's Business

54. The Company's primary product is Humira, the brand name for adalimumab, a tumor necrosis factor ("TNF") inhibiting anti-inflammatory drug administered by subcutaneous injection. Humira was approved for medical use in the United States in 2002, and costs approximately $5,400 for a supply of two injections, with patients generally taking one injection every two weeks.

55. Humira acts by TNF alpha, a signaling protein, and thereby reducing the body's inflammatory response. As a TNF blocker, Humira works by suppressing the immune system.

56. Humira is currently indicated for the following conditions: Rheumatoid Arthritis; Juvenile Idiopathic Arthritis; Psoriatic Arthritis; Ankylosing Spondylitis; Adult Crohn's Disease;

Pediatric Crohn's Disease; Ulcerative Colitis; Plaque Psoriasis; Hidradenitis Suppurativa; and Uveitis. For each of these conditions, alternative treatments exist.

57. Humira is critically important to the Company. Throughout the time period in issue , Humira was responsible for billions of dollars in revenues and contributed well over half of the Company's revenues. So important was (and is) Humira, that the Company cautioned investors that "[a]ny significant event that adversely affects HUMIRA revenues could have a material and negative impact on AbbVie's results of operations and cash flows."

58. For example, on April 5, 2013, the Company filed an amended annual report for the fiscal year ended December 31, 2012. The Company stated the following:

> **Strategic Objectives**
>
> AbbVie's long-term strategy is to maximize its existing portfolio through new indications, share gains, increased reach and geographic expansion in underserved markets while also advancing its new product pipeline. ***To successfully execute its long-term strategy, AbbVie will focus on expanding HUMIRA sales***, advancing the pipeline, expanding its presence in emerging markets and managing its product portfolio to maximize value.
>
> ***AbbVie expects to continue to drive strong HUMIRA sales growth in several ways. AbbVie seeks to expand the HUMIRA patient base by applying for regulatory approval of new indications for HUMIRA, treating conditions such as axial and peripheral spondyloarthritis and uveitis. AbbVie will also seek to drive HUMIRA sales growth by expanding its market share and its presence in underserved markets***. [Emphases added].

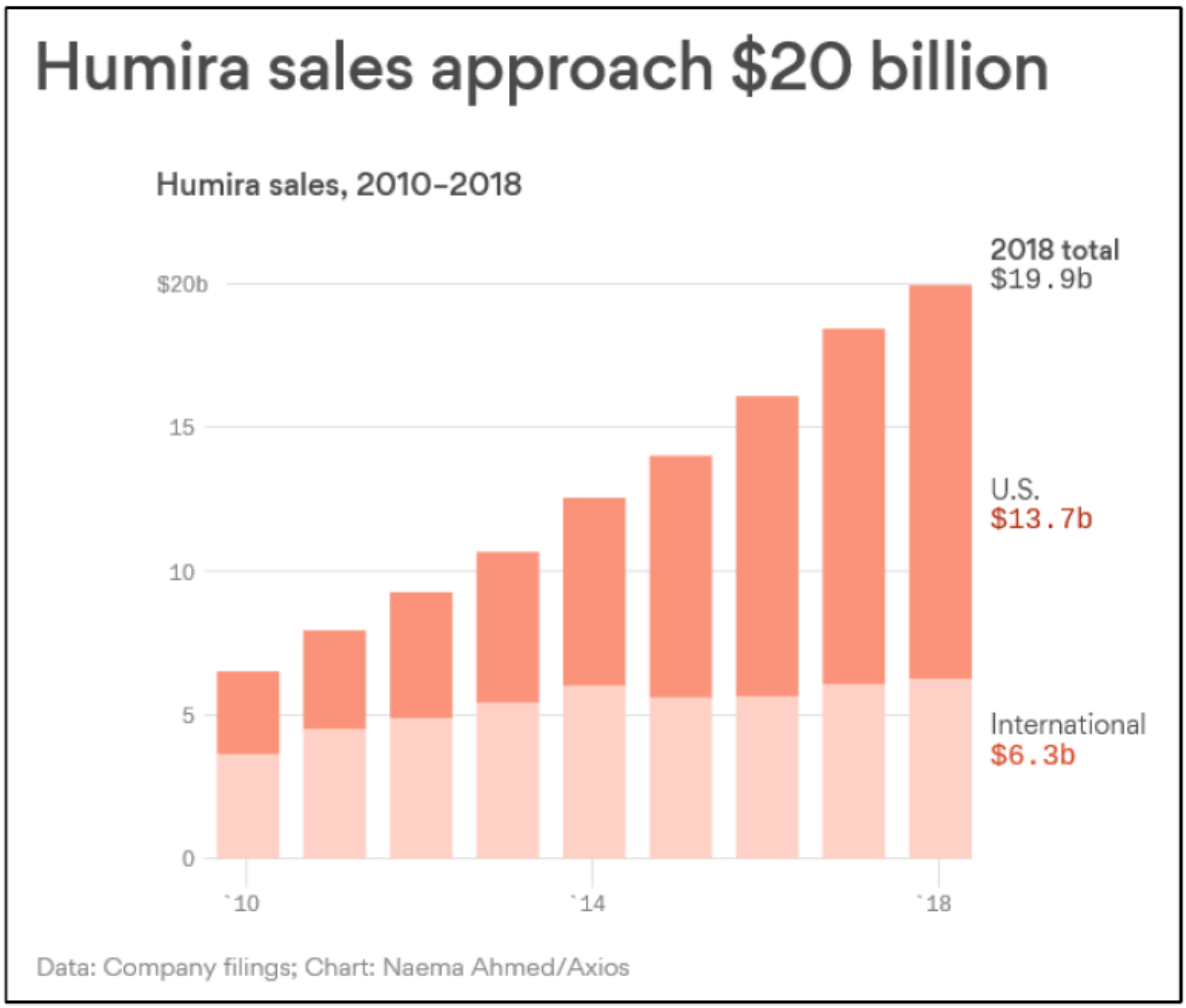
59. At the Morgan Stanley Healthcare Conference on September 10, 2014, Defendant Chase delivered a PowerPoint presentation that included a slide entitled "2014: Accomplishments to Date" that stated "Driving stellar growth from HUMIRA and several other products." In a PowerPoint presentation at the Credit Suisse Healthcare Conference on November 13, 2014, the Company also described HUMIRA as a "***Key Product***[] with Category Leadership Positions." (Emphasis added.)

60. Also, at a Global Health Care presentation on November 19, 2015, Defendant Chase stated: "***So HUMIRA has been a phenomenal growth driver for the company***. I mean, if you look

at how it's performed over the last few years, ***it's grown at over $1 billion per year this year. And of lately, this quarter, almost 20% growth on the brand. So HUMIRA is obviously incredibly important and a huge cash flow generator for the company***."

61. In an October 27, 2017 "Strategic Update" presentation, the Company reported it was "On-Track to Exceed" "Total AbbVie sales of ~$37 billion by 2020" and ***expected Humira sales in excess of $18 billion by 2020***. Thus, by 2020, Humira was still expected to be responsible for nearly half of AbbVie's sales revenues. In another slide, the Company noted that "Humira [is] expected to remain most widely prescribed front-line autoimmune agent" and "Humira to remain a significant part of ABBV cash generation story through 2025 and beyond."

62. The Company's sales numbers confirm its dependence on Humira. The drug was the highest-grossing drug in the world in 2014, achieving worldwide net sales on $12.5 billion, of which $6.5 billion was paid in the United States. In 2017, the Company sold $18.4 billion worth of Humira worldwide, accounting for 65% of AbbVie's revenue. In 2018, Humira earned $19.9 billion in revenue for AbbVie. The following chart shows AbbVie's revenues from Humira:



63. While Humira is the most prescribed drug in the world, it also tops the FDA's list of drugs with the most adverse event reports. Between 2013 and 2017, the drug was linked to about 209,000 adverse event reports, including more than 4,200 deaths. Accordingly, the FDA requires Humira to carry a "black-box warning" – the strictest form of drug warning. This label is necessary because Humira may increase the risk of serious and even fatal infections and may increase the risk of patients developing lymphoma or other cancers. More specifically, the label warns:

WARNING: SERIOUS INFECTIONS AND MALIGNANCY

See full prescribing information for complete boxed warning.

SERIOUS INFECTIONS (5.1, 6.1):

- **Increased risk of serious infections leading to hospitalization or death, including tuberculosis (TB), bacterial sepsis, invasive fungal infections (such as histoplasmosis), and infections due to other opportunistic pathogens.**
- **Discontinue HUMIRA if a patient develops a serious infection or sepsis during treatment.**
- **Perform test for latent TB; if positive, start treatment for TB prior to starting HUMIRA.**
- **Monitor all patients for active TB during treatment, even if initial latent TB test is negative.**

MALIGNANCY (5.2):

- **Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers including HUMIRA.**
- **Post-marketing cases of hepatosplenic T-cell lymphoma (HSTCL), a rare type of T-cell lymphoma, have occurred in adolescent and young adults with inflammatory bowel disease treated with TNF blockers including HUMIRA.**

Relevant Industry Codes and Regulatory Framework Governing Pharmaceutical Companies

64. The Company's sales and marketing of Humira are regulated by rigid industry codes and federal and state laws that limit what pharmaceutical companies and their sales representatives can do to market and sell their products.

65. Indeed, AbbVie told its investors and customers that the Company:

> ha[s] policies and procedures that guide employees as they conduct their day-today activities. They encompass relevant laws and regulations, including food and drug laws and laws relating to government health care programs. ***They also take into account industry best practices, including provisions of the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) Code of Pharmaceutical Marketing Practices, and the Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions with Healthcare***

> ***Professionals, as well as other applicable industry codes. We regularly update our policies to incorporate changes to the law and industry codes, including rules regarding gifts, meals and education we provide to healthcare professionals***.
>
> ***AbbVie also complies with legal, industry and relevant institutions' requirements regarding the interaction of our employees with health care professionals and organizations***. We comply with national, regional, state and other requirements regarding transparency about our relationships with individuals and entities involved in providing health care. As required, we track and report payments and transfers of values (such as meals) provided to health care providers and organizations. [Emphasis added].

66. The Company's sales of Humira are covered by the following: (1) the Office of Inspector General of the Department of Health and Human Services ("OIG") Guidelines; (2) the PhMRA Code; (3) the Code of Ethics for Nurses; (4) Illinois' Nurse Practice Act; (5) Florida's Nurse Practice Act; (6) California's Nursing Practice Act; and (7) the federal Anti-Kickback Statute. In addition, AbbVie also has its own Code of Business Conduct that it purports to adhere to in its business dealings.

The Company's Nurse Ambassador Program

67. Many Humira prescribers work in Rheumatology, Gastroenterology, and Dermatology practices. Quite often, these practices directly employ nurses, prior authorization staff, and other personnel to provide insurance and practice-related advice and counseling to patients. For example, office staff counsel patients on how to self-inject, assist them with insurance coverage and insurance forms, navigate specialty pharmacy and prior authorization requirements, answer patient questions, and conduct follow-ups to ensure patient adherence to prescribed medication regimes. These services are time-consuming and resource intensive. The staff members who perform them are professionals who command substantial salaries and benefits and are often overworked.

68. During the time period in issue, the Company offered a team of nurses at no cost to healthcare providers if – and only if – they chose to prescribe Humira. The Company has referred to the nurses by several titles, including "Nurse Ambassador," "Clinical Nurse Educator," "Nurse Educator," "Patient Ambassador," and "HUMIRA Ambassador." In sum, the Ambassador

Program was (and is) a network of nurses across the United States that provides services for patients using Humira that ordinarily would be delivered by the prescribing physician or by persons directly employed by that physician.

69. By furnishing "Nurse Ambassadors" to those healthcare providers – and only those healthcare providers – who prescribed Humira, the Company provided extensive, costly, and time consuming nursing-support services. The Company did so in the hope that it would encourage healthcare providers to write more Humira prescriptions and refills. If given the choice between two medications, one which comes with free nurses and administrative staff and another that requires the provider to pay professional salaries, healthcare providers are likely to factor the substantial nursing kickback into the prescribing calculus. These kickbacks motivated additional prescriptions and enabled the Company to reap greater sales revenues.

70. The Company contracted with QuintilesIMS ("Quintiles") to implement its Ambassador Program and used Registered Nurses employed through Quintiles to serve as representatives for direct dealings with doctors, office staff, and patients. Nurse Ambassadors also accompanied AbbVie sales representatives on visits to healthcare provider offices.

71. In general, Nurse Ambassadors visited healthcare providers with the goal of encouraging patient enrollment in the Ambassador Program. For example, the DOI Superseding Complaint includes a Humira enrollment form, which states: "Nursing Orders: My signature on this Enrollment Form indicates I am requesting a Registered Nurse to either (i) provide patient training on proper technique for self-administration of HUMIRA or, if needed, (ii) the administration of HUMIRA during the teaching visit. Order valid for up to one year."

72. The Company also provided Home Health Registered Nurses, or HHRN, as part of its Humira sales practices. HHRNs are registered nurses who train patients regarding injections and administer Humira injections to patients in their home. Patients gain access to an HHRN through enrollment in the Ambassador Program.

73. While providing significant value to the doctors' offices, Nurse Ambassadors' interactions with patients also serve as a stand-in for what otherwise would be a conversation between patient and physician. The Company's Nurse Ambassadors therefore affected the relationship between patient and healthcare provider by gaining access to patients and capitalizing on their vulnerability to ensure they filled their prescriptions and started to take and continued to use Humira.

74. The propriety of using Nurse Educators and Nurse Ambassadors, and the propriety of their contacts with patients, is controversial. One recent article, dated October 2, 2018, noted:

> "***This is the biggest topic in compliance circles, by far***," said Manny Tzavlakis, a managing partner at Helio Health Group, which advises drug makers on regulatory issues. "You're seeing patients becoming more of the center of commercial programs now. And this is the new area where the government can take on the industry."
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> ***
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> Both Sanofi and Biogen have received notices from the federal government seeking information about clinical educator programs. And an upcoming industry conference devoted exclusively to nurse educator programs lists U.S. attorneys from Newark, N.J., and Philadelphia as speakers.
>
> David Schumacher, a former deputy chief of the health care fraud unit in the U.S. attorney's office in Boston, ***said there are long-standing concerns about white coat marketing***. "If you're a nurse who can gain access [to the patient] and use professional bona fides to cloak the real objective — to promote the drug — that relationship is of concern, if it's coercive and can lead to overuse or inappropriate use of a drug," said Schumacher, now a partner at the Hooper, Lundy & Bookman law firm. "That type of arrangement is going to be very closely scrutinized." [Emphasis added].

Suarez Files a *Qui Tam* Action in the Northern District of Illinois

75. On October 5, 2015, Relator Lazaro Suarez ("Suarez"), a former Nurse Educator and Patient Ambassador who worked for the Company via its subcontractor Quintiles, filed a *qui tam* action against AbbVie and Abbott in the U.S. District Court for the Northern District of Illinois, captioned *United States ex rel. Suarez v. AbbVie, Inc.*, No. 1:15-cv-08928 (N.D. Ill. Oct. 8, 2015) (the "*Qui Tam* Action").

76. According to the *Qui Tam* Action, Suarez is a resident of North Bay Village, Florida who worked for AbbVie via its sub-contractor Quintiles Transactional Holdings, Inc. as a "Nurse Educator" and "Patient Ambassador" (the formal names for the positions he held) from approximately March 23, 2013 to October 2014 in the South Florida area.

77. According to the *Qui Tam* Action, Suarez was hired by Quintiles but reported to and worked with personnel at AbbVie, maintained an AbbVie email address, and worked exclusively in connection with AbbVie's drug Humira.

78. According to the *Qui Tam* Action, Suarez was successful during his tenure as an Ambassador, regularly earning recognition and awards for his role in the Program. On at least a dozen occasions, he received a financial reward (between $50-150) for his work, including four times during a single month. These rewards were related in practice to volume of Humira prescriptions.

79. According to the *Qui Tam* Action, Suarez was frequently held out as an example for his peers by his supervisors and was flown to train Ambassadors from throughout the country on numerous occasions. He regularly worked and communicated with Ambassador and sales teams in regions outside of Florida and beyond the southeastern United States, giving him first-hand experience with the nationwide implementation of the Ambassador Program and the scope of AbbVie's misconduct alleged herein.

80. According to the *Qui Tam* Action, Suarez had approximately 15 years of clinical experience before going to work for AbbVie. He received a B.S. in nursing in 2000 from the University of Miami and has been a Registered Nurse since 1996.

81. On February 12, 2018, Suarez filed an amended complaint. Suarez alleged violations of the False Claims Act and numerous state *qui tam* statutes in connection with AbbVie's kickbacks to prescribers to increase prescriptions and ensure patients' continued use of Humira.

82. On March 13, 2018, the United States filed a Notice of Election to Decline Intervention in the action. In so doing, the government requested that the relator's complaint and

amended complaint and notice of non-intervention be unsealed, but that all other papers on file in the action remain under seal.

83. In briefing filed with the Illinois federal district court, Suarez explained how the "Ambassador Program illegally pad[ded] profits under the guise of 'patient education,'" with appropriate citations to his amended complaint:

> Publicly, AbbVie claims the program is merely a patient education and support program. *Id.* ¶8. But, as Relator explains, once with patients one-on-one "Ambassadors do not provide and are not permitted to provide fair and balanced information." Id. ¶6. Instead, Ambassadors abandon their role as "educators" and deflect patients' frequent concerns about cancer and other risks in favor of overcoming patient objections and serving as the conduit to make sure that patients (though not the Government, which foots the bill) get financial assistance to help pay for HUMIRA. *Id.* ¶¶6; 83-117 […]. In trainings, Ambassadors practice deflecting patient concerns about side effects and referring the patient back to their doctor. However, as the Ambassador Program reduces interactions between patients and their health care providers, far fewer patients are likely to get their questions and concerns about safety answered. *Id.* ¶¶96-97.
>
> The Ambassador Program works to maximize financial returns for AbbVie by ensuring that patients start on and continue to take HUMIRA, regardless of facts that, if properly presented to medical offices, could counsel against continued use. *Id.* ¶¶ 58-59; *see also id.* ¶100 (managers directed Ambassadors to track patient data to "focus resources to have maximal return"); ¶¶112-117 (Ambassadors report adverse events such as injection site reactions, infections, and failure to improve (or worsening conditions) only to AbbVie and not to the patient's doctor or the FDA, and are instructed not to put in writing questions about patient interactions, including adverse events). Indeed, Ambassadors were evaluated based on prescription-based metrics, such as number of patients enrolled, that had nothing to do with education. ¶¶58-60.
>
> ***
>
> Capitalizing on the value provided, the Ambassador Program is touted to physicians in sales pitches and at speaker events. *Id.* ¶¶67-70; 78-82. Sales Representatives entice interest and overcome hesitancy to prescribe HUMIRA by painting a vivid picture that the Ambassador (and not the doctor or his busy staff) "will take that [patient] call," "will answer that [patient's] insurance question" and take "concerns about [calls to the office, dealing with billing, disposal] off the table" if the doctor chooses to prescribe HUMIRA. *Id.* ¶68. In fact, senior members of AbbVie's sales organization would identify higher prescribing "key accounts" that could benefit from the Ambassador program. *Id.* ¶72. In the early years of the program, through some point in 2013, Ambassadors actually accompanied Sales Representatives on sales calls to pitch and market the Ambassador Program. Regardless of whether Ambassadors

> actually join the Sales Reps, the messaging about the value of the program to physicians remains consistent. *Id.* ¶67. When describing whether to prescribe HUMIRA or another drug, doctors are enticed by the invitation that they should think of an Ambassador as "an extension" of their office. *Id.* ¶69. This attractive incentive even led some doctors to market themselves to patients by implying the Ambassador Program was a concierge service the doctor had arranged. *Id.* ¶81.

The State of California Intervenes in the Suarez Action and Files the DOI Superseding Complaint; the Company's Stock Price Falls

84. While the *United States ex rel. Suarez v. AbbVie, Inc.* action was pending in the Northern District of Illinois, the State of California initiated its own investigation regarding AbbVie's marketing practices of Humira. Those efforts – which included investigative depositions over a seven-month period – focused on AbbVie's use of kickbacks to physicians for the purpose of encouraging them to prescribe Humira, and its improper efforts to influence or misinform Humira patients through "nurse educators" or "nurse ambassadors" associated with AbbVie. In this regard, a spokesman for the State of California confirmed: "We conducted an investigation. ***We believe there is strong evidence that fraud was committed*** against private insurance companies."

85. Following the filing of the amended complaint in the Suarez action in the Northern District of Illinois on February 12, 2018, three days later, on February 15, 2018, Suarez filed a sealed *qui tam* action in state court in California, captioned *California ex rel. Suarez v. AbbVie Inc.*, No. RG18893169 (Cal. Sup. Ct.).

86. On September 6, 2018, the California DOI filed a notice of intervention (on behalf of the State of California) and took over the prosecution of the Suarez action.

87. On September 18, 2018, the California DOI publicly filed the DOI Superseding Complaint against AbbVie in Alameda County Superior Court on behalf of the State of California, alleging that the Company "systematically and repeatedly" violated anti-kickback laws by "pa[ying] healthcare providers to prescribe HUMIRA far in excess of the amount that they would have prescribed this expensive and dangerous drug absent the illegal kickbacks." The public version of the DOI Superseding Complaint (which laid out Defendants' fraudulent scheme in detail) is heavily redacted.

88. In connection with that filing, the California DOI called the Suarez action the "largest health care fraud case" in the California DOI's history and alleged that AbbVie violated the CIFPA and defrauded the state by approximately $1.2 billion.

89. In particular, the California DOI alleges that AbbVie provided kickbacks in more traditional forms (such as meals, cash, gifts, drinks, and trips), as well as more sophisticated forms, including "free and valuable professional foods and services." These services included marketing assistance, medical practice management technology, and free insurance processing services.

90. In connection with AbbVie's scheme, the California DOI's Insurance Commissioner Dave Jones stated that "***the [Nurse] Ambassadors were HUMIRA advocates hired to do one thing, keep patients on a dangerous drug at any cost***." As detailed in the DOI Superseding Complaint, the Nurse Ambassadors visited patients in their homes, giving AbbVie direct access that served its goal of promoting its drug over other constituencies. The Nurse Ambassadors, who had nursing backgrounds, were trained to downplay the risks of the medication and deflect patient concerns. Nurse Ambassadors also assisted doctors' offices with handling insurance authorizations and claim processing, saving those physicians significant time and money. AbbVie, however, would only provide that assistance if the physician prescribed (or continued to prescribe) Humira.

91. While much of the DOI Superseding Complaint is redacted, the following is known publicly regarding the key averments in that action:

> AbbVie has engaged in a far-reaching scheme including both "classic" kickbacks, including cash, meals, drinks, gifts, trips, and patient referrals, as well as more sophisticated ones, such as free and valuable professional goods and services to physicians to induce and reward HUMIRA prescriptions. For example, as part of its scheme, the Company gave providers "expensive and sophisticated proprietary software" at no charge to "increase HUMIRA prescriptions."
>
> The fulcrum of the fraudulent scheme, and among the most troubling aspects of it, is AbbVie's insertion of its own personnel directly into the homes of patients. When doctors prescribe HUMIRA, AbbVie sends registered nurses – which AbbVie calls "Ambassadors" – into patients' homes, representing them as an extension of the doctor's office. These Ambassadors save physicians time, money, and resources. At

no cost and considerable gain to the physician's office, AbbVie nurses provide patient care, pharmacy and insurance authorization assistance, open enrollment resources, paperwork help, advice on insurance products, and other services, all of which provide a substantial value, so long as the doctors prescribe AbbVie's drug instead of selecting another course of treatment.

These "Ambassadors" are required by AbbVie to take advantage of their nursing background and direct access to patients to serve AbbVie's financial interest in getting patients to take HUMIRA by downplaying its risks. Ambassadors provide unbalanced information: trained to tout the good while at the same time instructed on methods to avoid directly answering patient questions on the bad, even those pertaining to HUMIRA's serious and important side effects.

AbbVie's scheme as to HUMIRA is particularly egregious because its purpose is to induce prescriptions of a drug that carries deadly risks and that has single-handedly caused ratepayers in California to spend more money on insurance. Specifically, HUMIRA has FDA boxed warnings (commonly referred to as "black box" warnings) – the strictest prescription-warning level – because of its risk of death by cancer or infection.

Given HUMIRA's black box warnings, before injecting HUMIRA, patients deserve advice from a healthcare provider (and provider staff) that is free from the taint of kickbacks to induce prescriptions, or any motive other than the best-interests of the patient. Unfortunately, as a result of AbbVie's kickback scheme, too many Californians unwittingly receive HUMIRA prescriptions from providers who selected and prescribed the drug while taking kickbacks from AbbVie

Suarez was originally interested in the Nurse Ambassador position because he understood he would be an educator helping patients with challenging diagnoses. He grew concerned that this was a subterfuge, however, and that his role was instead focused on rewarding prescribing physicians and obfuscating his role with respect to patients and patient care.

Suarez was correct to develop suspicions: what he and his colleagues did not know was that they were effectively being used by AbbVie as runners and cappers, people working at the behest of AbbVie in connection with its concrete, internal financial goals.

For example, Suarez visited physicians' offices alongside sales representatives, with his Nurse Ambassador services touted as a benefit of prescribing HUMIRA. Indeed, AbbVie referred to him and other nurse Ambassadors as "an extension" of the doctor's office, available in exchange for choosing an AbbVie drug.

Overall, Suarez felt that the focus of the Ambassador program was getting and keeping patients on HUMIRA to maintain and increase AbbVie's profits. Suarez, as a medical professional, was troubled by this emphasis on the bottom line. He attended national

> trainings wherein Nurse Ambassadors were trained to hide HUMIRA's serious cancer and infection risks from patients. In response to patient concerns about serious potential side effects, he and others were explicitly trained to deflect the questions and reply that while they were not able to discuss these side effects, they would help find a way to "get you your HUMIRA for five dollars or less." As a Nurse, he felt compelled to blow the whistle on AbbVie's fraud.
>
> Additionally, AbbVie employed healthcare providers to promote the use of Humira at higher dosages and frequencies than those indicated on the drug's label (off-label escalated dosing).

92. In connection with the filing of the DOI Superseding Complaint, Adriane Fugh-Berman, a professor at Georgetown University Medical Center, stated: "This is marketing laundered through your doctor. . . . You're providing services to a patient so that patient will be motivated to stay on a drug which may not be the best drug for them and may not be the most cost-effective drug."

93. On October 19, 2018, the Company removed the case to federal court. During a February 7, 2019 hearing addressing the potential remand of the action back to state court, counsel for the State of California stated: "We did a very extensive prefiling investigation in this case" and that "there is no more important consumer case, I think, before the State of California right now than this one. I think it's an incredibly important case for the State." In addition, the State's counsel confirmed that "we will be pursuing this case very vigorously on behalf of the State of California, the people of California. And it's an extremely important case for the public of California."

A Former Nurse Ambassador Corroborates Suarez and the State of California's Allegations

94. FE-1[2], a Nurse Ambassador at AbbVie in 2013 for two months, has been a nurse for over thirty years. She explained that she only briefly worked for AbbVie because she would not drink "the Kool-aide" associated with the Ambassador program. During her time as a Nurse Ambassador, she reported to Lane Murray, an AbbVie manager, and to Catherine Poisson, a Quintiles manager.

[2] Information regarding FE-1 is taken from the securities class action entitled *Holwill v. AbbVie, Inc., et al.*, 18-cv-06790 (N.D. Il.) ("Securities Class Action")

95. Upon information and belief, according to FE-1, the Nurse Ambassadors underwent a five-week training program prior to going out into the field. The training began with five days of training in Chicago, followed by home-based training for two weeks, and then finished with two full weeks in Chicago. On the second to last night of training in Chicago, the nurse ambassadors met with their assigned sales representatives. Personnel from both AbbVie and Quintiles conducted the Nurse Ambassador training. FE-1 specifically recalled that one of the people leading the Ambassador training was not a nurse, which she found odd as she could not understand how a non-nurse could train nurses.

96. Upon information and belief, despite all of this training, FE-1 said the Nurse Ambassadors' "only role" was to get patients committed to Humira and teach them how to self-administer the Humira injection. She felt as though "the whole purpose" of the Ambassador program was to get "patients onto Humira" "for $5.00 a month."

97. Upon information and belief, FE-1 said that her experience at AbbVie as a Nurse Ambassador was different than her prior nursing jobs. First, she was not allowed to take a patient's vital signs, which made her "pretty uncomfortable" as she felt like taking vital signs was a "safety precaution" when injecting a patient.

98. Second, she explained that as a Nurse Ambassador, she was not allowed to provide any medical advice to the patients. During training, "they didn't tell us one time, they told us 400 times" that if a patient had a complaint or concern, the Nurse Ambassadors were told to tell the patient to call the patient's doctor. Indeed, FE-1 recalled that they were told "a thousand times" that nurse ambassadors could not tell a patient to "take two Tylenol" or administer Benadryl if a patient experienced a side effect while taking Humira.

99. While the Ambassador training discussed the side effects of Humira, the Ambassadors were told repeatedly that they were not supposed to review the side effects with the patients with whom they met. When FE-1 asked during the training session who would go over the

side effects with the patients, she was informed that AbbVie had training that they provided to the physicians.

100. Upon information and belief, this inability to discuss side effects with patients went against FE-1's professional commitment to and belief in transparency, especially with regard to pharmaceuticals. As a nurse, FE-1 felt like it was her duty to review the possible side effects of the drugs with the patients, but AbbVie said that the Ambassadors were "not supposed to educate" the patients about side effects. If the patient ever asked about potential side effects, the Ambassador could only tell him or her to speak with their physician.

101. Upon information and belief, FE-1 also expressed that there was "absolutely" an overlap between the role of the Nurse Ambassadors and the sales representatives. For example, she recalled meeting with her sales representative and a pharmaceutical distributor during her brief time at AbbVie. She asked why she needed to participate in the meeting because it had no clear relevance to her job as a Nurse Ambassador (which was to teach patients how to self-inject Humira) and where the drug came from was of "no concern" to her.

102. Upon information and belief, in addition, FE-1 reported that she knew Lazaro Suarez and that she interacted with him directly during training and after the training. While she did not know him well, she said he came across as "very professional" and a "real stand-up guy." During the training, the two discussed that all of the nurses seemed "tickled to be there" [working for AbbVie] and that they were making "unbelievable" money for what seemed to be a very easy job.

Federal and State Laws Prohibit Kickbacks to Providers and Payments to Induce or Reward Referrals

103. The False Claims Act ("FCA") imposes civil liability on any person who "knowingly presents or causes to be presented" a false or fraudulent claim for payment to the United States. 31 U.S.C. § 3729(a)(1)(A). A claim is false under the FCA if the defendant supplied a "kickback" as an impetus for the underlying transaction. 42 U.S.C. § 1320a–7b(g).

104. The Anti-Kickback Statute ("AKS") makes it illegal for individuals or entities to knowingly and willfully "offer[] or pay[] remuneration (including any kickback, bribe, or rebate) ... to any person to induce such person ... to purchase, ... order, ... or recommend purchasing ... or ordering any good ... or item for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(2).

105. Violations of the AKS occur where pharmaceutical companies provide valuable products or services to procure use of their drugs. Indeed, if even one purpose of an offer of value is to pay kickbacks, that is sufficient under the law.

106. Compliance with the AKS, 42 U.S.C. § 1320a-7b(b), is a condition of payment under the federal health care programs. Whether or not a claim complies with the AKS is material to the government's decision to pay that claim, as a matter of law. *See Guilfoile v. Shields*, 913 F.3d 178, 190 (1st Cir. 2019). Thus, it does not matter if the medical care or item provided was also medically necessary; filing a kickback-tainted claim triggers liability.

107. The Office of the Inspector General ("OIG") has explained that arrangements under which physicians are relieved of "financial obligations they would otherwise incur" pose a "significant risk" leading to an inference "that the remuneration may be in exchange for generating business," thus serving as a kickback inducing the prescription. OIG Supplemental Compliance Program Guidance for Hospitals, 70 Fed. Reg. 4858-01, 4866.

108. As the OIG has expressly set forth:

> if goods or services provided by the [drug] manufacturer eliminate an expense that the physician would have otherwise incurred (*i.e.*, have independent value to the physician) . . . the arrangement may be problematic [under the AKS] if the arrangement is tied directly or indirectly to the generation of federal health care program business for the manufacturer.

OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 FR 23731-01.

109. Moreover, under the anti-kickback statute, neither a legitimate purpose for an arrangement (*e.g.*, physician education), nor a fair market value payment, will necessarily protect

remuneration if there is also an illegal purpose (*i.e.*, the purposeful inducement of business). *Id.* at *23737.

110. Similarly, OIG has, in several advisory opinions, identified "suspect characteristics" of arrangements among sellers, sales agents, and purchasers that "appear to be associated with an increased potential for program abuse." Among those "suspect characteristics" are arrangements wherein:

(a) Compensation of the agent is based on percentage of sales;

(b) There is direct contact between the sales agent and physicians in a position to order items or services that are then paid for by a Federal health care program;

(c) There is direct contact between the sales agent and Federal health care program beneficiaries;

(d) The program uses sales agents who are health care professionals or persons in a similar position to exert undue influence on purchasers or patients.

See OIG Advisory Opinion 98-10 (August 31, 1998).

111. The OIG has further expressly warned against the risks of pharmaceutical companies using medical professionals, like nurses, to promote its products. Specifically, OIG explains that risks of fraud and abuse are "compounded" where a "health care professional is involved in marketing activity." This type of marketing is "closely scrutinized under the anti-kickback statute because physicians and other health care professionals are in an exceptional position of public trust and thus may exert undue influence when recommending health care-related items or services." OIG Advisory Opinion 11-08 (June 14, 2011).

112. Violation of the AKS is a felony punishable by fines and imprisonment and can also result in exclusion from participation in federal health care programs. 42 U.S.C. § 1320a-7b(b)(2) and 42 U.S.C. § 1320a-7(b)(7). State laws have similar prohibitions.

False And Misleading Statements About A Drug's Use Are Prohibited

113. Drug Manufacturers are prohibited from disseminating materials that are "false and misleading," such as those that only present favorable information when unfavorable information exists, that exclude mandatory information about the safety and efficacy of the drug use, or that present conclusions that "clearly cannot be supported by the results of the study." 21 C.F.R. § 99.101(a)(4).

114. In fact, the FDA has promulgated extensive regulations on the content and form of prescription drug advertising. Advertisements "shall present a true statement of information in brief summary relating to . . . effectiveness." 21 C.F.R. 202.1(e)(6)(i).

115. FDA regulations also enumerate a number of tactics that can render advertising "false, lacking in fair balance, or otherwise misleading, or otherwise violative" of section 502(n) of the Act. 21 U.S.C. § 352. These requirements apply to industry sponsored or controlled activity whether it is educational or promotional. *See* Guidance for Industry: Industry-Supported Scientific and Educational Activities, 62 Fed. Reg. 64,093, 64,096-99 (1997). Regulations on prescription drug advertisements are found in 21 C.F.R. § 202.1, and further underscore the importance of true statements related to side effects.

The Provision Of Free Drugs

116. There are also limits on benefits pharmaceutical companies may provide that subsidize or provide free drugs to Government Payor patients.

117. If a patient is not financially needy, providing a free drug, which puts the patient on the path to continuing to take that drug, can be improper. Here, as shown below, AbbVie used its Ambassadors as a conduit to connect patients with free drugs, which was outside of the stated purpose of the program.

FRAMEWORK FOR PRESCRIPTION DRUG PAYMENT UNDER GOVERNMENT PROGRAMS.

The Medicare Program Pays Certain Of The Cost Of Prescriptions For Its Enrollees

118. Medicare Part D covers pharmacy-dispensed outpatient drugs including Humira. Part D prescription drug plans may exclude from coverage drugs that are not "reasonable and

necessary" to the patient's treatment. 42 U.S.C. § 1395w-102(e)(3)(A). Specific coverage policies and decisions are generally made by sponsors who contract with the Center for Medicare and Medicaid Services ("CMS") to provide such coverage and are responsible for making coverage determinations in accordance with statutes and regulations.

119. The pharmacies where prescriptions of Humira are filled agree to provide pharmaceuticals to Medicare Part D Plans ("PDPs") for Medicare patients that they serve, and the PDPs in turn reimburse these pharmacies for the cost of the drugs, plus a fixed dispensing fee meant to provide the pharmacies with a profit for providing services to Medicare patients. PDPs (or MA-PDPs) are administered under contract with CMS by private entities such as Blue Cross Blue Shield plans, large commercial insurers such as Humana, and pharmacy benefit managers.

120. Every time a beneficiary fills a prescription covered under Part D, PDPs must submit a summary called the prescription drug event, or PDE, record. The PDE record contains drug cost and payment data that enable CMS to administer the Part D benefit. CMS uses the PDE record to calculate reimbursement to PDPs for the cost of drugs, plus an amount meant to provide the PDPs with a profit for administering the PDP.

The Medicaid Program Pays The Cost Of Prescriptions For Its Enrollees

121. Medicaid is a joint Federal-State program that pays for medical assistance for individuals and families with low incomes and relatively few assets. Although pharmacy coverage is an optional benefit under federal Medicaid law, all States currently provide coverage for outpatient prescription drugs to all categorically eligible individuals and most other enrollees within their Medicaid programs.

122. The state Medicaid programs adhere to federal guidelines. Federal statutes and regulations restrict the drugs and drug uses that the Federal Government will pay for through its funding of state Medicaid programs. Federal reimbursement for prescription drugs under the Medicaid program is limited to "covered outpatient drugs." 42 U.S.C. §§ 1396b, 1396r-8(k)(2)- (3). Covered outpatient drugs are drugs that are used for "a medically accepted indication." 42 U.S.C.

§ 1396r-8(k)(3). A medically-accepted indication is listed in the labeling approved by the FDA, or that is included in one of the drug Compendia identified in the Medicaid statute. 42 U.S.C. § 1396r-8(k)(6).

123. Providers who fill prescriptions for Medicaid enrollees submit their Medicaid claims for reimbursement by "batching" them daily and submitting them electronically to states. These claims include the claims for prescriptions of Humira that were falsely induced pursuant to the unlawful Ambassador Program.

124. As part of each electronic claim, the office and pharmacies affix their unique Medicaid provider identification numbers, which serve as electronic stamps indicating that, as Medicaid providers, they are in compliance with all applicable federal and state laws.

125. The offices and pharmacies are reimbursed on a monthly basis by the states for all approved claims.

126. Through the Federal Medical Assistance Percentage ("FMAP"), State Medicaid administrators obtain the Federal Government's share of the offices' and pharmacies' reimbursements by submitting a quarterly Form 64 to CMS. The funds made available to the state remain federal funds, in a Federal Reserve account, until they are drawn by the state and used to pay the offices' or pharmacies' claims. 42 C.F.R. § 430.30(d)(3), (4). Thus, claims submitted to state Medicaid agencies, including those in the various states, are presented to the Federal Government within the meaning of the FCA.

127. The Federal Government also "approves," within the meaning of the False Claims Act, the claims submitted and paid through the Medicaid program. When a state presents its Form 64 (*i.e.*, the quarterly report of actual expenditures) to CMS, the amounts of any fraudulent claims the state paid will be included in those reports. Based on the information in the reports, CMS determines and approves whether the claims that the state paid with federal funds were appropriate. If CMS determines that certain claims paid by the state were improper, CMS may recoup the

amount of the erroneously expended funds by reducing the amount of money provided to the state during the next quarter.

128. The Form 64 constitutes the United States' means for approving and paying the amount of federal funds expended by the state. To the extent these reports overstate the amount of federal funds to which the state was entitled because of false or fraudulent prescriptions, they constitute false records or statements caused to be made or used to get false claims paid and approved by the United States.

Other Government Programs Similarly Cover Prescription Drug Costs

129. Other Government Programs adhere to similar rules in determining a drug's eligibility for reimbursement.

130. In addition to Medicaid and Medicare, the Federal Government reimburses a portion of the cost of prescription drugs under several other federal health care programs, such as CHAMPUS/TRICARE (administered by the Department of Defense); CHAMPVA (administered by the Department of Veterans Affairs); and The Federal Employee Health Benefit Program (administered by the Office of Personnel Management, for federal employees).

ABBVIE DEPLOYED ITS OWN "NURSES" TO INDUCE PRESCRIPTIONS OF HUMIRA

Background On Humira

131. Humira ("Human Monoclonal Antibody In Rheumatoid Arthritis") is the brand name for Adalimumab, a tumor necrosis factor (TNF) inhibiting anti-inflammatory drug. It is a powerful and expensive drug that is a treatment option for a range of autoimmune conditions. Originally approved as a second-line treatment for Rheumatoid Arthritis, Humira is now indicated for Rheumatoid Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis, Juvenile Idiopathic Arthritis, Crohn's Disease, Ulcerative Colitis, Plaque Psoriasis, Hidradenitis Suppurativa, and Uveitis.

132. Humira was first approved 2002 and has since grown to become the world's bestselling drug. Its sales account for the vast majority of AbbVie's total revenues.

133. Humira must be injected subcutaneously. Once acclimated, patients generally need to be injected, or to inject themselves, approximately every two weeks. Typically, once a patient starts on Humira, they will be advised to stay on it indefinitely. Indeed, patients are warned that if they abruptly stop treatment with Humira (rather than tapering off slowly) they may have a "severe" reaction or "flare up" of their condition after which they may not respond to Humira or other similar treatment.

134. Humira carries a black box warning for serious and life-threatening side effects, including lymphoma, tuberculosis, and other infections.

Prescribing Humira Is Expensive For Doctors

135. Doctors and their staff are heavily burdened by administrative work. This work keeps doctors from seeing additional patients, which also drives payment.

136. In a study conducted by a general medicine practice with five physicians, the doctors reported receiving an average of 23.7 calls from patients per day, with questions ranging from acute medical issues, administrative questions (*e.g.*, prior authorization for insurance), and questions about test results and clinical follow up, among other things.[3] In addition, the physicians received an average of 16.8 patient emails per physician per day addressing similar topics.[4] Following that study, the practice "hired additional front-desk staff and medical assistants to handle the increased tasks associated with the comprehensive management of chronic diseases"—thereby freeing up more physician time to see patients.[5]

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[3] Baron, Richard J., "What's Keeping Us So Busy in Primary Care? A Snapshot from One Practice." *New England Journal of Medicine*, 362;12 April 29, 2010.

[4] *Id.*

[5] *Id.*

137. Time spent on such administrative work is generally not reimbursed by payers, but seeing patients is.[6] One study estimated that physicians spend up to 20% of their workday on these tasks.[7]

138. Physician practices must interact with numerous health plans in the U.S. multi-payer system, each with their own requirements and procedures. Moreover, interactions increase with plans' attempts to "manage care," such as requiring prior authorizations for many specialist, imaging, and hospital services. Each health plan offers many different insurance products to consumers, and each may have its own formulary (or list of approved drugs); prior authorization requirements; and rules for billing, submitting claims, and adjudication.[8]

139. Within this framework, Humira is particularly challenging for doctors as it is an expensive drug that requires a great deal of non-billable support from the doctor and their staff. For that reason, many physicians were historically disinclined to prescribe it. This all changed when AbbVie took these considerations off the table by eliminating the need for the doctor's and their staff to do this work, instead providing a Registered Nurse to do it for them.

140. Humira prescribers work in Rheumatology, Gastroenterology, and Dermatology practices. These practices typically employ nurses and professional staff to provide general advice and counseling to patients and assistance with insurance and billing for prescriptions. As to Humira, for example, professional office staff counsel patients on, among other things: how to self-inject, help them with insurance coverage and insurance forms (including, where applicable, obtaining prior authorizations from their insurer), navigate specialty pharmacy and prior authorization requirements, answer patient questions, and conduct follow-ups to ensure patient adherence to prescribed medication regimes.

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6 *See* Chen, Melinda A. et. al. "Patient Care Outside of Office Visits: A Primary Care Physician Time Study." *Society of General Internal Medicine*, September 2, 2010.

7 *Id.*

8 Morra, Dante et al. "US Physician Pratices Versus Canadians: Spending Nearly Fourt Times As Much Money Interacting with Payers." *Health Affairs*, August 2011. Available at https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2010.0893.

141. These services are time consuming and resource intensive. The staff members that perform them are professionals that command substantial salaries and benefits and are often overworked.

142. The financial impact of excessive administrative complexity on physician organizations can be dramatic. In one study of a typical ten-physician practice, it was estimated that excessive administrative complexity cost the practice more than $250,000 per year. Another physician organization saw 32 percent growth in the staffing of its professional billing office over a six-year period, to 250 full-time equivalents. The expansion was needed to help deal with administrative complexity and was independent of the practice's programmatic growth.[9]

143. Even just one aspect of these services—dealing directly with insurance companies—is a significant cost to the physician. In a May 2009 survey of physicians and practice administrators published in Health Affairs, physicians themselves reported spending forty-three minutes per day (nearly three weeks per year) interacting with health plans on behalf of patients—including looking at prior authorization requirements, pharmaceutical formularies, claims, credentialing, contracting and data on quality. For professional staff (*i.e.*, Registered Nurses, Medical Assistants, and Licensed Practical Nurses) these numbers are even higher— spending 3.8 hours per physician per day interacting with health plans, and clerical staff devoting up to 7.2 hours per physician per day.[10]

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[9] Blanchfield, Bonnie et al. "Saving Billions Of Dollars—And Physicians' Time—By Streamlining Billing Practices." *Health Affairs*, June 2010. Available at https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2009.0075.

[10] Casalino et. al., "What Does It Cost Physician Practices to Interact With Health Insurance Plans?" *Health Affairs*, May 14, 2009, available at https://www.healthaffairs.org/doi/10.1377/hlthaff.28.4.w533.

144. On average, this works out to a cost of at least $68,859 per physician per year (in 2009 dollars) for interacting with health plans alone. For medical specialist practices, the amount increases to $78,913 per physician per year.[11]

AbbVie Used The Ambassador Program To Meet Doctors' Resource Needs

145. Recognizing the challenges to increasing Humira prescriptions (and profits), and eyeing physicians' resource needs that stood in the way, AbbVie developed and deployed a marketing scheme called the Ambassador Program.

146. Since early 2012, AbbVie (originally as Abbott) partnered with Quintiles Transactional Holdings, Inc.—now IQVIA—to launch the Ambassador Program around the time the sales curve for Humira appeared to be flattening. The purpose of this nationwide marketing strategy was to bolster Humira's volume and market share, protect it from encroachment by competitors and bio-similars (including, for example, Enbrel), and to maximize revenues and profits.

147. The Program, detailed below, was designed to overcome resistance to prescribing Humira and reward physicians for doing so. It was tremendously successful in these efforts—with a commensurate boost to AbbVie's bottom line. Indeed, following an initial boost to its profits from Humira due to the Ambassador Program, AbbVie acted quickly to expand the Program (and its results) into territories throughout the United States. As of May 2014, the Company hit a self-described milestone: a senior executive wrote to the entire Ambassador team that 10,000 patients were supported by an Ambassador. That same year, Humira was the highest-grossing drug in the world, achieving global net sales of $12.5 billion, $6.5 billion of which was paid in the U.S. alone. The success has only continued with the expansion of the Program across and throughout the United States—U.S. sales of Humira from 2015 to present totaled $55.8 billion.

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11 *Id.*

148. The Ambassador Program provides independent value to doctors who prescribe Humira because it saves them time and money they (or their staff) would otherwise have to spend on patient care and administration. Through the Program, at no cost and considerable gain to the physician's office, AbbVie nurses provide valuable professional services including patient care (including regular in-person visits and communications with patients in response to questions about their treatment and disease states), pharmacy and insurance authorization assistance, open enrollment resources, paperwork help, advice on insurance products, and other services and support.

149. In practice, this includes hours-long visits to patients in their homes and addressing myriad patient questions and concerns that would otherwise be directed to the physician's office (including those having nothing to do with Humira or the diagnosis). For example, according to the *Qui Tam* Action, Suarez frequently worked with patients to address their computer and other technology issues in fulfilling their prescriptions or dealing with their doctors' offices and insurance companies. Patients, with access to a Nurse directly in their own home, also frequently used the opportunity to raise questions and concerns about their medical histories and other health issues (indeed, a review of non-Humira related medical history was part of the Ambassadors' jobs). And, notwithstanding a purported policy to direct medical treatment back to the physician, in the moment, Nurse Ambassadors would often draw on their past clinical work to assuage patient questions and concerns, thereby preventing yet another call to the doctor. This was the entirely foreseeable result of the required application of the program, where general patient health was a standard part of the intake.

150. According to the *Qui Tam* Action, Suarez also frequently served as a translator for Spanish-speaking patients, including calling Medicare with them to translate and verify their coverage for the drug under their current Medicare plan, and assisting in their switching to another plan if needed.

151. Also as part of his patient visits, according to the *Qui Tam* Action, Suarez and other Ambassadors were provided with Humira travel kits (akin to a lunch box or cooler) that could be

used, among other things, to keep the drug cool when away from refrigerator access. This resource, and the direction from the Ambassador provided along with it, stood in place of numerous calls to doctor's offices about, for example: (1) how to travel with Humira; (2) the appropriate temperature to maintain the drug; (3) whether or not to skip a Humira dose; (4) related concerns about diagnoses and disease states.

152. Without an Ambassador, these types of questions (and many others)—and the time required to answer them—fall to the physician and their staff. Having AbbVie nurses step in to do it for them offers tremendous value and time-saving to physicians, thereby incentivizing them to prescribe Humira. If given the choice between two medications, one which comes with free nurses and administrative staff and another that requires the provider to pay professional salaries, the provider cannot but help factor the substantial nursing kickback into their prescribing calculus.

153. A typical Ambassador conducts about 20 patient visits a week. As discrete nursing visits, the collective value of these is spent working with physician offices and doctors, and other functions, and traveling.

154. When visiting doctor's offices apart from patient visits, Ambassadors reinforce the benefits of the Program to the physician and their office staff and providing information and training about the resources available through the Ambassador Program. According to the *Qui Tam* Action, Suarez recalls discussing with doctor's and their staff, on numerous occasions, topics including: specific follow up questions about individual patients he had visited, information about the number of patients he was able to see and service through the Program and the services offered, and information about providing free or reduced cost Humira to low income patients through the AbbVie Patient Assistance Foundation.

155. Doctors recognize the benefits of the Ambassador Program to their advantage beyond the direct relief of their staffing needs and costs, leveraging the Program to their marketing advantage as well. For example, in the competitive South Florida dermatology market for wealthy older patients, physicians came to brag about the program and imply it was a service the doctor had

arranged for his or her own patients. Hollywood Dermatology had a "Concierge" service and represented the Ambassador Program as a benefit to their patients as needed. One high-prescribing doctor in that practice was Dr. Eduardo Weiss.

156. According to the *Qui Tam* Action, other examples of high-prescribing dermatologists who actively have touted the Ambassador Program in marketing their practices, and worked especially closely with Ambassadors, included Dr. Francisco Kerdel (a company speaker and affiliate of among the highest prescribing, if not the highest prescribing, dermatology offices in South Florida, Florida Academic Dermatology Center), Dr. Tory Sullivan, and Drs. Pedrozo and Weiss.

AbbVie Intentionally Designed The Ambassador Program To Increase Its Profits

157. Although it is publicly represented as a "patient education" initiative, the Nurse Ambassador program is actually designed, and functions, to protect and boost AbbVie's profits from the prescription and sale of Humira.

158. According to the *Qui Tam* Action, in an email from Elaine Sorg, Vice President of U.S Immunology, Ms. Sorg urged Ambassadors that "patient enrollment in this program is ***critical*** to the long term success of HUMIRA" and noted that she "look[ed] forward to seeing enrollment numbers that exceed our expectations." (Emphasis added).

159. According to the *Qui Tam* Action, AbbVie Senior Management routinely applied pressure to increase the reach of the Ambassador Program. For example, during a June 17, 2013 Ambassador team meeting, it was emphasized that Senior Management wanted "a solid 2-3 enrollments per week with a goal of 4-5 new enrollments by Q4"). At the time, the stated goal of the program was to ensure that 80% of new Humira patients across the country received a face to face meeting and injection training from an Ambassador.

160. According to the *Qui Tam* Action, AbbVie's own metrics used to evaluate the Program substantiate its intended purpose to induce and reward Humira prescriptions. AbbVie tracks the success of the Ambassador program by conducting "return-on-investment" calculations

and analyses, weighing the costs of the program (and, likely, the legal risks) against the huge profits generated by Humira's expanding market share and volume. Such internal "ROI" analysis (which is not publicized or shared with the investing public, despite its positive results) is a classic "***red flag***" demonstrating that the Program's primary purpose is financial, not scientific or medical.

161. According to the *Qui Tam* Action, AbbVie also tracks the increased prescriptions that result from the Program. Tellingly, as reflected on the Field Coaching Logs, AbbVie evaluates Ambassadors' performance on prescription-based metrics: (a) number of patients enrolled, (b) number of unique live visits, (c) percent of patients with the drug, (d) number of offices launched, and (e) total number of offices enrolling, rewarding additional accounts won, and prescriptions induced, by the Ambassador. These metrics are all unrelated to patient education, the ostensible purpose of the program.

162. Tellingly, Ambassadors' compensation is tied to prescription metrics (and thus, not related to education). In fact, all of the Ambassadors' variable compensation depends on these bottom-line, prescription-related metrics. Ambassadors can earn up to approximately 20% of their overall compensation in quarterly bonuses that are entirely dependent on the number and/or percent of offices that launch the program and/or patients who take Humira. Similarly, AbbVie managers and executives with responsibility over the program have significant financial incentives tied to meeting or exceeding prescription and market-share quotas.

163. These core metrics for evaluating and compensating Ambassadors reflect how senior personnel evaluate the Ambassador Program as a whole and determine the resources to put into it. Managers have stressed to Ambassadors that the prescription-based metrics demonstrate the value of the Ambassador Program to senior level AbbVie personnel, especially in the high adherence rate of patients who are prescribed Humira. Managers in the Ambassador program report only the core business-related metrics to AbbVie decision-makers.

164. Importantly, that patients obtain assistance in learning to inject themselves (something they would otherwise, if they needed the help, be done in connection with the doctors'

offices) does not alter the fact that the marketing program called the Ambassador program was a kickback. The kickbacks provide independent value to doctors in eliminating expenses they would otherwise incur and are thus unlawful.

Ambassadors And Sales Representatives Ensure Financial Success Through Marketing The Program Directly To Doctors

165. AbbVie has ensured that Ambassadors maintain active, various contacts with doctors' offices in which they discuss the Ambassador Program and provide additional services to doctors' offices even beyond the substantial time they spend with patients. The contacts further the initial pitch that the Ambassador is an extension of the doctor's office.

166. According to the *Qui Tam* Action, AbbVie is well aware, as reflected in its Ambassador Guidelines, that Ambassadors are not supposed to function as sales representatives if they are not providing fair and balanced information regarding side effects (which is legally required of sales representatives). Consequently, the Guidelines purport to direct that Ambassadors "will be restricted from being part of recurring call plan visits to doctors because they are not part of AbbVie's sales force and any extensive interactions could have HR and other implications."

167. Nevertheless, Ambassadors work with, and report to, Sales team personnel as well as to managers in the Ambassador department.

168. Ambassadors play a crucial role in interfacing with physicians and marketing their free and valuable professional services (and thereby influencing prescription decisions). AbbVie uses the Ambassador Program as a powerful tool to access doctors and other prescribers (particularly those who have previously refused or resisted the efforts of AbbVie sales representatives to pay them detailing visits to promote AbbVie products). Ambassadors are often able to get a foot in the door with a physician's office where a sales representative could not.

169. According to the *Qui Tam* Action, through a variety of in-person meetings and tactics and a collaboration of the Sales and Ambassador teams, AbbVie presents the Ambassador Program to prescribers as a value add to the practice—a free "extension" of their otherwise paid-

for resources. Members of the Sales Team that Suarez worked with, including John Little, regularly pitched the Program to doctors using these terms.

170. According to the *Qui Tam* Action, an early job description for the position of Ambassador Manager described the program as follows, with express reference to the program's connection to AbbVie's "commercial organization": "Interact[ing] closely with commercial organization to drive increased brand performance and retention on the HUMIRA brand by ensuring 'Best in Class' support and education regarding myHUMIRA platform services."

171. According to the *Qui Tam* Action, as of March 2013, AbbVie, via Quintiles, hastily changed the description of the program to an "educational based program designed as a resource for patients living with auto-immune diseases that have been prescribed specific medications. Patient Ambassadors provide education about specific disease treatments, and resources to help patients better begin and manage their disease state and resources associated with their prescribed medication. Patient Ambassadors are responsible for participating in one-on-one communications with patients as well as appropriate medical professionals within the associated treatment process. Since the program is strictly educational based, Patient Ambassadors, do not provide medical advice or work clinically within this role." This was false.

172. To avoid detection of the real marketing nature of the program, Ambassadors have been cautioned about their written communications with the Sales team, explicitly directed to use "limited" communications over email with sales. According to the *Qui Tam* Action, in a call agenda for May 20, 2013 team call, one agenda item, "COMMUNICATION WITH SALES" cautioned Ambassadors to have "CAREFUL CAREFUL COMMUNICATION (phone vs. email) with sales colleagues." Further they are instructed to refrain from using the word "Humira" when leaving a message. However, even with communications discouraged so as not to leave a paper trail, Ambassadors' coordination with the sales team is a key part of the strategy to identify and target prescribers, and key evidence of the true goals of the Program.

Ambassadors Visited Doctors With Sales Representatives

173. In the early years of the Program, and until some point in 2013, Ambassadors regularly accompanied sales representatives on sales calls to physicians' offices to pitch the Ambassador Program. This arrangement begs the key question of why representatives of a patient education program would coordinate with sales representatives. The explanation, of course, is that the program was designed to increase prescription volume, not educate patients.

174. The sales pitch to doctors has been consistent, however, regardless of whether the Ambassadors have personally joined the sales representatives on their call visits. According to the *Qui Tam* Action, Suarez attended periodic meetings with the sales team and the local District Manager to discuss business planning and sales calls. Frequently, sales representatives told Suarez to expect a call from a particular doctor or his or her office based on the sales representative's having just pitched the Ambassador Program and its benefits to the doctor. In these calls, Suarez was expected to affirm the pitch and close the deal with the physician.

175. According to the *Qui Tam* Action, in the marketing pitch, sales representatives, including John Little, among others, detail exactly how the Ambassadors save the doctors and their staff substantial time: "we will take that [patient] call," "we will take that [patient's] insurance question," "doctor, we will take your concerns about [calls to the office, dealing with billing, disposal] off the table." And to doctors, time is money.

176. According to the *Qui Tam* Action, after touting the program, the sales representative (at times accompanied by the Ambassador) "closes" with the question of whether the doctor would write more Humira if the time and service related concerns were "off the table."

177. According to the *Qui Tam* Action, doctors responded positively to the marketing pitch and opted to prescribe Humira as a result of the Ambassador Program. Among the doctors who responded positively to the marketing pitch and opted to prescribe Humira as a result of the Ambassador Program was Dr. Avelino A. Guiribitey. Among those who dramatically increased their prescriptions were Dr. Alejandro Pedrozo and other doctors identified herein.

Ambassadors Conducted Targeted Visits To Doctors Informed By Sales Strategy

178. According to the *Qui Tam* Action, based on their knowledge of which providers are generally high-prescribers of injectable biologics, senior members of AbbVie's sales organization identify key accounts that might benefit from receiving visits from Ambassadors.

179. High-prescribers are the key target of additional marketing efforts for the Program. Ambassadors attend "launch" or "re-launch" events where they meet with doctors and their staff once a doctor has joined the Ambassador Program, or re-joined it. For example, according to the *Qui Tam* Action, Suarez attended a re-launch meeting with Dr. Robert Sarro's office. Dr. Sarro and his assistant had been persuaded that the Ambassador Program would "make their lives easier."

180. Such visits are a successful marketing strategy. For example, according to the *Qui Tam* Action, in or about August 2014, Suarez attended a lunch with a physician where he described the scope of the services available through the Ambassador program, as well as the amount of time Ambassadors have available for each patient. Following that lunch, AbbVie's Senior Immunology Specialist reported that the lunch was "extremely effective" and that they were "looking forward to continuing this optimization strategy in our top offices." This strategy, of course, was tied to marketing Ambassadors to high prescribers.

181. Key accounts also receive targeted, less formal visits and office drop-bys from Ambassadors to market the Program. According to the *Qui Tam* Action, Suarez had at least four such calls in August 2014 alone, in which he described the Ambassador Program and touted its benefits to doctors and their staff.

182. According to the *Qui Tam* Action, these visits are expressly for the purpose of marketing. For example, according to the *Qui Tam* Action, in a May 2013 Ambassador team call, one agenda item encouraged Ambassadors to drop off brochures at a physicians' office because it "gives you another reason to go into the office" which is effective because the Ambassador himself is the "best brochure" for the Program.

183. Ambassadors also visit, or communicate with, doctors' offices to respond to specific questions about specific patients, including if the patient has routed an administrative question to the doctor's office rather than to the Ambassador.

184. According to the *Qui Tam* Action, managers warn Ambassadors not to formally record all the time they spend with doctors, including these marketing efforts. Ambassadors typically enter their daily activities on the CRM (Customer Relations) section of the Sales Force database (*e.g.*, first live visit, pre- and post-calls to patients after their first few injections). However, according to the *Qui Tam* Action, on the informal monthly ride alongs, managers tell Ambassadors that if they are only doing a drop off of materials or a quick program orientation, they should not document an office call in the database.

185. According to the *Qui Tam* Action, Ambassadors are explicitly instructed to disguise their efforts to market to doctors in their written records. For example, an Ambassador team call the week of July 17, 2013, in which the team discussed communication with doctor's offices and received direction to avoid leaving a paper trail when stopping by a doctor's office to drop off Ambassador Program materials, (the exact words on the call agenda are "don't document").

186. Given the frequency of those "short" visits, and their intimate role in effectuating the Ambassadors' regular duties in visiting doctors, the injunction against logging these visits had the result of dramatically underestimating the time Ambassadors spent with doctors and their offices.

187. This directive from the Company's top evidences explicit policies and efforts to conceal the marketing and sales purposes of the Program.

188. In addition, according to the *Qui Tam* Action, Ambassadors are expected to provide, and do provide, free materials to patients and office staff (Humira travel kits (valued at approximately $15 to $20 dollars or more); "Talking Training Pens" used to train patient on how to inject themselves) on request. These travel kits are coolers that enable patients to travel with Humira and maintain the drug at the appropriate temperature, thereby reducing patient questions (and the

time required to answer them) on how to safely travel with the drug, and can be used to keep a variety of materials cool while in transit.

189. According to the *Qui Tam* Action, Ambassadors are expected to work, and do work, with office staff to bring preprinted Prior Authorization and other benefit forms to doctors' offices.

190. According to the *Qui Tam* Action, AbbVie also issued an initiative to place dedicated Humira terminals in doctors' offices that print benefit verification forms and other insurance-related documents, with a goal to deploy 2000 such terminals. At the time Relator left his employment with AbbVie, there were already approximately 200 such terminals placed by AbbVie in doctors' offices as an additional free benefit of prescribing Humira.

Ambassadors Attended Speaker Dinners To Pitch And Represent The Program

191. According to the *Qui Tam* Action, AbbVie used to require Ambassadors to attend as many speaker events as possible, and ensured that Ambassadors were seated at tables next to key potential prescribers so they could pitch the program directly. Examples of doctors who were influenced in their prescribing behavior by speaker dinners include Dr. Jerome R. Obed and Dr. Varee N. Poochareon.

192. At some point, around the same time that AbbVie took the precaution not to actually have the Ambassadors attend every sales call, AbbVie also changed the requirement that Ambassadors regularly attend speaker dinners. However, throughout the period in which that policy was in place, AbbVie's deployment of Ambassadors to these dinners was designed to influence prescription decisions.

AMBASSADORS ENGAGE IN MARKETING, AND ALSO PROVIDE IMPROPER PATIENT CARE

193. The Ambassador Program capitalizes on, and violates, patients' trust of nurses and their need for care and assistance and uses that trust to ensure that the patients start and continue to use Humira.

194. According to the *Qui Tam* Action, underscoring the misleading conduct, AbbVie provides Ambassadors with company business cards with their Registered Nurse (R.N.) status displayed and instructs Ambassadors to brag about their history as nurses to patients. On the other hand, AbbVie management also tells Ambassadors not to publicly refer to themselves as healthcare providers, or even to their "patients" as "patients."

195. For example, according to the *Qui Tam* Action, AbbVie management praised Suarez in a formal review in August, 2014 for his "sincere relationships with patients." But, in field observations from manager Sean Garrison, in the section on "patient observation interactions," Mr. Garrison wrote to Suarez that "while you build fantastic rapport with your patients…by using the word 'people' vs 'patient' you may be able more appropriately identify your role as an educator vs a clinician. It may open up some more/different dialogue as well."

196. Although they step in to provide one-on-one consultations to patients, AbbVie's Ambassadors do not provide, and are not permitted to provide, fair and balanced information in these meetings. Instead, AbbVie instructs the Ambassadors to deflect patient's questions about side effects, like Humira's cancer risks. In trainings for the Ambassador Program, role play scenarios demonstrate the response that "[cancer] is a great question for your doctor; I am here to get you your Humira for five dollars or less." The issue, of course, is that with an AbbVie-paid Ambassador serving as their direct point of contact about Humira, it reduces interactions between patients and their health care providers, so far fewer patients are likely to get their questions and concerns about safety answered.

AbbVie's Ambassadors Work Directly With Patients So That Doctors Don't Have To

197. According to the *Qui Tam* Action, when assigned a new client, Ambassadors begin with a call to set up an appointment. Notably, in a material percentage of the time, the patient has not yet decided whether to fill the prescription, and thus Ambassadors highly influence the decision to take Humira in the first place. Patients frequently told Suarez that they likely would not have started on Humira if he had not contacted them.

198. According to the *Qui Tam* Action, through these initial calls, the Nurse Ambassador steps in to assist in fulfilling the Humira prescription and answering patient questions about it. Because the Ambassador is there to answer these questions, the doctor doesn't have to. However, reducing interactions between the healthcare provider and the patient in this way severs critical decision-making points between doctor and patient, and replaces it instead with a pharmaceutical company representative standing in to guide and counsel patients.

199. According to the *Qui Tam* Action, after the initial contact, the Ambassador then sets up an in-person meeting, typically in the patient's home. The initial patient visit takes an average of one hour, and as many as two-and-a-half. Typically about one third of the visit is spent making sure the patient has access to reimbursement or, as needed, free drugs. The rest relates to the patients, their diagnoses, and their personal experiences. Ambassadors are told that if the patient is not doing 75% of the talking, something is wrong. During these visits, the Ambassador is expected to discuss the patients' experience with the underlying disease and their concerns, and to familiarize themselves with the patient and their needs more broadly (*i.e.*, family, financial, and living situation), consciously engendering a trust relationship with the patient, who perceives the Ambassador as an extension of his or her doctor's office.

200. This perception is understandable, especially given that doctors, at AbbVie's urging, tell patients that "a nurse will be contacting you" about starting on the drug.

201. According to the *Qui Tam* Action, during these initial and follow up meetings, Ambassadors advise patients on their diagnoses and treatment plans. For example, Ambassadors would advise patients on ways in which to limit adverse events at injection sites, including by taking Benadryl prior to administering a Humira injection.

202. According to the *Qui Tam* Action, Ambassadors also discuss with patients their backgrounds and related diagnoses, including comorbidities and co-mortalities to the diagnosis resulting in a Humira prescription. During these interactions, patients regularly raised additional questions and concerns about symptoms and health concerns that may or may not have been related

to Humira or their underlying diagnosis treated by Humira. Of course, as Registered Nurses, Ambassadors could draw on their experiences in offering suggestions and guidance, including assuaging concerns and thus preventing the need for additional calls to the doctor (saving the doctors time, and money, in the process).

203. In presenting Humira, according to the *Qui Tam* Action, the Ambassadors show the patient a company-created video that addresses how Humira works. Generally, the Ambassadors discontinue the video when the video turns to the more serious side effects of Humira. Ambassadors believe this is not a problem because in any case patients foreseeably have stopped paying attention to the dense and rushed material around that time (given patients have someone right in front of them with whom to discuss the drug). Thus, especially combined with their inability to discuss side effects, Ambassadors foreclose avenues of giving fair and balanced information to patients.

204. Similarly, and again instead of being meaningfully fair and balanced, according to the *Qui Tam* Action, the Ambassador is supposed to hand the patient the long and complex package insert presented in tiny print, explain that it would take far too long to review on the spot, and recommend that the patient review it him or herself. AbbVie likely knows that the dissemination of the package insert to patients is a potential defense to its systematic failure to allow Ambassadors to convey fair and balanced information to patients. AbbVie has set up its systems to require the Ambassadors to regularly order a monthly or quarterly quota of package inserts, regardless of whether they need them.

205. The Ambassador's job is to overcome patients' uncertainty when it comes to the decision to start or continue on Humira. Given that their performance and variable pay is tied to prescription-related metrics, the Ambassador's success in their job is explicitly tied to their success in doing so.

206. Crucially, when patients have questions about Humira's serious side effects, the Ambassadors abandon their role as "educators" entirely and, despite being experts on Humira and

the conditions it treats, must withhold the most important safety information from the patients, instead referring patients to their doctors.

207. Tellingly, it is only in the area of the drug's serious risks where the Ambassadors are not permitted to speak. According to the *Qui Tam* Action, the Ambassador Guidelines expressly provide that if a patient "expresses uncertainty over using the Ambassador, the HCP treatment plan, or desire to continue or start treatment with HUMIRA for any reason (such as the patient says 'I am afraid of getting cancer from using Humira'), the Ambassador shall refer the patient back to his/her physician for a further discussion."

208. According to the *Qui Tam* Action, if a patient reports an adverse event, the Ambassador reports the incident only to AbbVie. The Ambassadors do not report the events to patients' doctors, even though the Ambassadors may well be visiting the patient's doctor's office for various office-assistance reasons. Not only is there no opportunity for Ambassadors to report adverse events on their weekly reporting, but Ambassadors are instructed not to put in writing any questions at all about patients interactions, not just those limited to adverse events.

209. And while they are instructed to tell the patients to call their doctors about adverse events, Ambassadors do not ensure that they do so—despite regularly joining phone calls with patients for other calls (namely to ensure payment).

210. According to the *Qui Tam* Action, approximately ten percent of Suarez' patients experienced an adverse event while taking Humira, including injection site reactions, failure to improve (or worsening conditions) and infections.

211. Ironically, according to the *Qui Tam* Action, Suarez knows of at least one instance in which a patient who tried to report an adverse event to a doctor's office was simply routed back to the Ambassador by the doctor's office so that the Ambassador (and not the doctor) could address the patient's concerns.

212. According to the *Qui Tam* Action, following the initial, major visit, Ambassadors typically make two additional in person visits. Thereafter, Ambassadors then typically switch to

phone contact with the patients. All of the Ambassadors log their patient visits on company databases. On these databases, there are pre-sent drop boxes and there are no spaces available for characterizing the calls or for reporting adverse events—precluding the ability to create a written record of the same.

Ambassadors Are Directed To Hide And
Distort Their Patient Interactions In Written Records

213. According to the *Qui Tam* Action, AbbVie leadership directs Ambassadors to obscure the true nature and actual functioning of the Program in their written records and communications.

214. According to the *Qui Tam* Action, Abbvie leadership has instructed the Ambassadors not to refer specifically to Humira in writing up patient visits, despite the fact that Humira is the only reason for their presence in the patient's home. As manager Lane Murray wrote to Suarez: "Thanks for sharing your Magic Moments with the team!! I appreciate the fact that you took the time to be a leader on this by encouraging our team to follow your lead and submitting their Moments of Wow! …….PS Also, don't forget that we cannot utilize the name of the drug when writing these up. . . (instead, say 'current therapy' or their 'current drug' etc….) We'll discuss writing these up a little more tomorrow!" In the follow-up discussion, Mr. Murray, consistent with other messaging from other AbbVie managers, expressed concerns about creating a paper trail about Humira.

215. Indeed, according to the *Qui Tam* Action, Ambassadors are specifically and repeatedly told that if they have a question about what they permissibly can do in the course of their patient interactions, they should not write it down and call their supervisor instead. This point was made during Ambassador training programs and reiterated frequently by AbbVie management personnel, including Tracey Calamita, Lane Murray, and Sean Garrison.

216. Taken together, the prohibitions detailed herein against mentioning Humira by name, against using the word "patients" to describe the patients, against recording time with doctors,

and against recording adverse events have served to limit the record of the Ambassadors' actual work, and evidence AbbVie's leadership knowledge and intent in deploying the Ambassador program to make money, but hiding that true motive from scrutiny by preventing the development of a written record.

Leveraging Patient Interactions To Inform AbbVie's Marketing Efforts

217. According to the *Qui Tam* Action, another key objective of the Ambassador Program and goal in the initial patient meetings is to get patients to enroll on the website "MyHumira." This website reflects AbbVie's effort to use the Ambassador program to target the marketing of Humira through the Ambassador Program. MyHumira is a service platform through which AbbVie compiles specific data about each patient's personal information, including geographic location, disease profile, provider information, Humira usage, payment source information, and Ambassador interaction, among other things. This allows AbbVie to track macro information about the drug and the doctors that prescribe it, in order to better target its marketing efforts.

218. According to the *Qui Tam* Action, every one of the Suarez' managers, including Tracey Calamita, Reed Morton, Donald Lane Murray, Sean Garrison, and Maya Stewart (National Ambassador Manager), repeatedly reminded the Suarez (and other Ambassadors) to carefully track patient data so that AbbVie could better focus its resources. The common phrase was to "focus resources to have maximal return."

Serving As The Conduit To Keep Government Payor Patients On Humira During the Coverage "Donut Hole"

219. The Program was designed to reach and did reach government payor patients, on whose behalf claims were submitted to Medicare and Medicaid. In this context, Ambassadors occupy a crucial role in assisting patients with coverage for Humira, tasks that (as noted above) require the Ambassadors to spend about a third of the first visit on payment information.

220. Some of this work is simply replacing what otherwise is the work of the doctors' office staff in dealing with insurance companies. AbbVie has instructed Ambassadors that while they may not call insurers directly, they can (and should) be on the phone when patients call and can (and should) encourage patients to initiate calls to learn about coverage. This includes government insurers like Medicare and Medicaid.

221. According to the *Qui Tam* Action, AbbVie representatives provide insurance assistance, including helping patients navigate open enrollment periods in their insurance plans, and respond to patient questions about insurance coverage and copays, all in order to ensure their continued coverage. In so doing, AbbVie representatives fulfill the role of professional staff and office administrators, and field questions about deductibles, co pays, coinsurance, and health savings accounts.

222. While Ambassadors encourage commercial patients to obtain Humira co-pay cards, they take a different but equally effective approach with Government Payor patients. For that population, Ambassadors are required to contact Medicare to determine the patients' payment status: namely, how much the patient must pay in the first couple of months of treatment, when the payment is relatively manageable, and at what point the patient's coverage stops during the gap period before coverage resumes (the so-called "Donut Hole").

223. At that point, armed with that information, the Ambassador refers the patient to the "Patient Assistance Foundation."

224. According to the *Qui Tam* Action, AbbVie has given away tens of thousands of free dosages of Humira that, among things, and intentionally, help Part D Medicare patients fill the "Donut Hole." The Ambassadors have a crucial role in connecting patients with the AbbVie Patient Assistance Foundation that provides these free drugs.

225. According to the *Qui Tam* Action, as AbbVie managers told Suarez, true, independent charity foundation assistance for Humira runs out in the first couple of months of the

year, but AbbVie's own Patient Assistance Foundation has ample free supply to give patients during their Medicare Part D payment gap period.

226. According to the *Qui Tam* Action, in Suarez' experience, all patients (save one or two who appeared to be quite wealthy) were able to obtain free drugs from AbbVie through the Patient Assistance Foundation based on how AbbVie's Patient Assistance Foundation laxly defined "need."

227. As touted at national meetings attended by all the Ambassadors, AbbVie gave out substantial amounts of free drugs per year. According to the *Qui Tam* Action, Suarez recalls the amount from 2013 to be 94,000 dosages. This degree of assistance to Government Payor patients enables hundreds or thousands of patients to get launched on this costly drug that, as addressed above, is difficult to discontinue usage.

228. Finally, and further underscoring the attention AbbVie pays to Medicare reimbursement information, AbbVie management provides information about open enrollment periods for Medicare plans and requires Ambassadors to try to push their patients into plans that maximize reimbursement for Humira. According to the *Qui Tam* Action, in Suarez' experience, the open-enrollment period for government insurance, in or about November of the two years he worked as an Ambassador, were particularly busy, with calls to Medicare and Medicaid along with patients to secure and verify coverage for Humira occurring multiple times a week throughout that window.

Examples Of The Ambassador Program In Practice

229. Like other Ambassadors, according to the *Qui Tam* Action, Suarez was expected to memorialize "success" stories in which the outcome of the interaction with a patient was to get them on Humira, or in which a physician responded particularly well to the Ambassador Services. These stories were often distributed in email in what the company referred to as "Magic Moments," "Moments of Wow," "Making Magic" incidents, and/or "Highlight Stories."

230. According to the *Qui Tam* Action, examples that Suarez saw or penned include anecdotes where patients said "I really wasn't gonna take this, if you hadn't called me I just wasn't ready for this…." and an anecdote where a "client [was] thinking about stopping…" but was convinced by the Ambassador not to.

231. In or about December 2014, according to the *Qui Tam* Action, Suarez emailed his team summarizing "10 very common THANK YOU comments" that Ambassadors report hearing from patients as moments of "WOW." Fourth on the list, he noted patients thanking Ambassadors because "Medicare Part D is so confusing, thank you for being there with me as I called on this…"

232. According to the *Qui Tam* Action, the following serve as additional illustrative examples of the type of patient work Suarez undertook as part of the Nurse Ambassador program. These are representative cases only.

233. In or about summer 2013, Suarez received a patient assignment to an elderly woman living near 95th street and the Interstate 95 freeway in Miami. The patient was a psoriasis patient, and Suarez visited her in her home for injection training and orientation to the Ambassador Program. While there, they discussed the patient's insurance coverage, and Relator learned she was having difficulty obtaining Medicare coverage for her prescription. Relator and the patient called Medicare that day and were able to arrange for coverage.

234. In or about July 2013, Suarez sent his supervisors an account of a "Happy Ending" for a Medicare patient living in the Little Haiti area of Miami. Prior to visiting this patient, Suarez visited the offices of Dr. Sullivan in Miami to "reinforce[e] the Nurse Ambassador Role." After the visit to Dr. Sullivan, Suarez relayed they had "obviously made an impression" because the doctor then "activated" Suarez' Nurse Ambassador services. However, as Sales Representative John Little warned Suarez, Dr. Sullivan would use the Program for the "tough" cases that would otherwise require him and his staff significant extra work.

235. Suarez visited the patient, who was legally blind, in his home in the Little Haiti neighborhood, and assisted in presenting an appeal to obtain assistance from the Patient Assistance

Foundation during the Medicare coverage gap (also known as the "donut hole"). Suarez helped gather proof of income (noting Medicare on his bank statement) and the appeal was ultimately successful.

236. According to the *Qui Tam* Action, this success story was shared within the broader team in an email from Maya Stewart, the National Ambassador Manager, recognizing Suarez for his work. Notably, after this initial experience dealing with a "challenging" patient of Dr. Sullivan's, Dr. Sullivan was impressed and encouraged by the hands-on services in the Ambassador program. He continued to write Humira prescriptions and took to assigning his more "difficult" or "challenging" patients to Suarez.

237. According to the *Qui Tam* Action, on or about October 18, 2013, Suarez received public praise in a "Patient Highlight" email sent to the team by Maya Stewart. Suarez was working with a psoriasis patient in Miami who, when he turned 65 in April 2013, had changed insurance to Medicare. He was no longer able to afford Humira on the new plan. As she related, this patient's doctor had been previously reluctant to use the Ambassador Program and decided to "test" the Program with this challenging issue. Suarez was assigned to the patient and worked with him to appeal the overage denial from Medicare. The patient was again denied, and Suarez escalated the issue and again appealed it. The prescription for Humira was ultimately approved for Medicare coverage following Suarez' work.

238. According to the *Qui Tam* Action, after the success in obtaining Medicare coverage, and as related to AbbVie colleagues in the email from Ms. Stewart, both the patient and the physician were "thrilled at the level of support provided by the Ambassador Program." In fact, the physician "communicated that they will be encouraging each patient to enroll in the Ambassador Program due to the high level of support provided." In the same email, Stewart noted that Medicare coverage story, and the physician's positive response, was "forwarded to the sales organization and Senior Leadership."

239. Also, in or about October 2013, according to the *Qui Tam* Action, Suarez and colleagues communicated about a particularly difficult case of an 83-year-old Medicare patient, originally from Alaska but living in Nogales, Arizona at the time. This patient had been flying from Nogales, Arizona to Seattle, Washington to see a dermatologist who prescribed him Humira. Ultimately, Roxanne— another Ambassador based in Nogales—visited the patient in his home in Nogales, and "coached and watched him inject."

240. According to the *Qui Tam* Action, in the latter half of his employment with AbbVie, in or about fall 2013 or spring 2014, Suarez recalls visiting a female patient in the Miami area who worked at the local animal shelter. The patient suffered from psoriasis and was experiencing difficulty in securing her Medicare coverage for her Humira prescription. Suarez stepped in to assist, and they successfully contacted Medicare to verify her coverage.

241. According to the *Qui Tam* Action, absent access to Discovery, Suarez cannot state the amounts paid by these physicians for administrative work and staffing support. However—and in the context that the average cost per physician per year to interact with health plans alone is approximately $68,859--on information and belief, these physicians, and others whose patients were enrolled in the Ambassador Program, saved money in having to pay less in their staff time and overtime pay, and in hiring and employing staff members to address administrative work for patients. Further, these doctors (and others) had more time and capacity to see (and bill for) more patients because Ambassadors stepped in to address patient and administrative work for Humira that otherwise would have occupied the doctor's time.

THE AMBASSADOR PROGRAM WAS NATIONWIDE
AND OPERATED CONSISTENTLY THROUGHOUT THE COUNTRY

242. During his tenure with AbbVie, according to the *Qui Tam* Action, Suarez was a frequent attendee, and presenter, at trainings for Ambassadors from throughout the United States.

243. In or about April 2013, according to the *Qui Tam* Action, Suarez attended a training meeting at headquarters in Chicago as he onboarded to the Program along with several others.

During that meeting, he recalls receiving instruction to "stop thinking like a nurse" or words to that effect.

244. In or about September 2013, AbbVie held a national meeting for the Immunology team in Puerto Rico, including both Ambassadors and Sales Representatives. At this meeting, according to the *Qui Tam* Action, which Suarez attended, Ambassadors received training on patient interview techniques, including deflecting questions about Humira's serious side effects. Ambassadors attended that training from throughout the United States.

245. In or about January 2014, according to the *Qui Tam* Action, Suarez presented at an Ambassador Training in Chicago, titled the "Q1 Initial Sales Training Class" in which he provided training at AbbVie's headquarters for new Ambassadors from across territorial regions

246. At a national sales meeting in March 2014, according to the *Qui Tam* Action, Suarez was selected as a team captain for his region. In this position, he trained Ambassadors from throughout the Southeast region, including from Georgia and North Carolina.

247. In or about September 2014, according to the *Qui Tam* Action, Suarez attended a National Immunology Sales Team meeting in San Antonio, Texas. This meeting included joint meetings and training sessions for Sales Representatives and Ambassadors from across the country.

248. According to the *Qui Tam* Action, Suarez also gained first-hand exposure to the nationwide operation of the Program through working as a translator for other Ambassadors. According to the *Qui Tam* Action, Suarez is a fluent Spanish speaker and was frequently asked to translate for Spanish speaking patients over the phone. For example, he assisted Ambassador Mary Willingham with a Spanish speaking patient in Boston, as well as Candice Whitten with a Spanish speaking patient in the Charlotte, North Carolina region, and assisted other Ambassadors with their patients on numerous other occasions.

249. Through his role as a national trainer, as well as through routine communications with Ambassadors and Sales Representatives in regions outside of Florida, according to the *Qui Tam* Action, Suarez observed the work of other Ambassadors throughout the country.

250. According to the *Qui Tam* Action, in addition to these first-hand observations from Suarez' own experience as to the nationwide scope of the conduct alleged, AbbVie also uses a "low touch" program for patients who already have been taking Humira for longer periods which was also designed to offer a sweeping geographic reach. Specifically, established patients communicate with company-paid nurses who work from home only by telephone. Second, as of approximately fall 2014 the company piloted a program ("Operation Dakota") in which prospective Humira patients living in sparsely-populated areas have contact with Ambassadors by telephone or video, so that no market would be beyond the reach of the Ambassador Program.

MATERIALLY FALSE AND MISLEADING STATEMENTS

251. On October 25, 2013, Defendants caused the Company to file a Form 8-K with the SEC announcing its third quarter 2013 fiscal results ("3Q 2013 Press Release"). In the 3Q 2013 Press Release, Defendant Gonzalez stated that the Company's "third-quarter performance demonstrates the strength and durability of our product portfolio and the continued execution of our key strategic priorities as an independent biopharmaceutical company[.]"

252. On that same day, the Company held its Third Quarter 2013 Earnings Conference Call. During the call, Defendant Gonzalez commented on the growth of Humira, and stated, in pertinent part:

> I am pleased with the performance of our product portfolio including Humira, which delivered more than 19% global operational growth in the quarter. ***This strong growth was driven by several factors, including continued robust market growth resulting from increasing penetration across therapeutic categories and geographies; market share gains, particularly in the GI segment where our UC launch is progressing ahead of our expectations; and we delivered this performance despite the entry of new competitors into the category***. [Emphasis added].

253. On the call, Defendant Chase also discussed AbbVie's plans to increase Humira's market penetration, stating, in pertinent part:

> And we now expect SG&A expense to be approximately 27% of sales in 2013, ***reflecting increased investment in our key brands, including Humira, where we are pursuing opportunities to further increase penetration rates across indications***. [Emphasis added].

254. In response to a question from JP Morgan Analyst Chris Schott regarding the particulars of higher spending on Humira promotional programs, Defendant Gonzalez described the framework AbbVie had built to defend and grow Humira's market share, stating, in pertinent part:

> If you talk about Humira spend, one of the things I would say to you is, as we approached the beginning of this year one of the things that we knew is that we were going to face some new competitive challenges. ***And in anticipation of that we did some things from an investment standpoint that we thought would put us in a position to be able to defend and still grow our share.***
>
> ***And I would say if I look at the results 9 or 10 months into it we are pretty happy with the investment that we made there, because it's given us back a pretty healthy return and it is really -- it has allowed us from a competitive standpoint to really deal with new competition in a very effective way***.
>
> As far as HCV is concerned, I think as Scott pointed out, a significant part of this is really built around the performance of the product. We have done a lot of market research, and when you look at prescribing preference of physicians, the first five, six attributes are all related to performance of the product -- cure rates in different populations.
>
> So as the competitive environment rolls out and as we get to our second-generation product, I think we will then take another incremental step in this particular disease treatment paradigm that will be difficult to beat. I think it is incredibly difficult to get performance that is better than this -- or at least what we anticipate.
>
> ***And then it will be all about how you built your infrastructure, how well established it is. That will make it difficult***.
>
> You look, again, at the anti-TNF market. Think how difficult it is for a new competitor to break into that market. And it is because of both the performance of the product and the value that it provides ***and the established infrastructure that is in place that has a lot of experience at being able to drive those products***. [Emphasis added].

255. The statements contained above were materially false and/or misleading because Defendants Gonzalez and Chase misrepresented and failed to disclose the following adverse facts pertaining to the growth of Humira's sales and Company's strategy for maintaining and growing Humira's market share and sales, which were known to Defendants or recklessly disregarded by them. Specifically, Defendants Gonzalez and Chase made materially false and/or misleading

statements and/or failed to disclose that: (i) AbbVie's strategy to maintain and increase the sales growth of its blockbuster drug, Humira, relied in part upon systematic illegal kickbacks and unlawful sales and marketing tactics; (ii) such practices would foreseeably lead to heightened scrutiny by state governments and agencies; and (iii) as a result, the public statements of Defendants Gonzalez and Chase were materially false and misleading at all relevant times.

256. On January 15, 2014, AbbVie presented at the JPMorgan Healthcare Conference. During that presentation, Defendant Chase stated in pertinent part:

> Certainly an important component of our performance over the past year has been Humira and we continue to be very, very pleased with its trajectory. Since 2006, we have added really $1 billion of Humira sales growth each year. We will provide more specifics on our 2013 performance later this month, but I can tell you that once again we delivered stellar growth from our flagship product in 2013.
>
> ***Humira has a number of unique attributes that set it apart from its competitive peers***. These include a strong and differentiated clinical profile, a label that supports the use across the broadest spectrum of autoimmune conditions, strong managed care positions and ***importantly development, regulatory, manufacturing, commercial organizations that are truly exceptional.*** [Emphasis added].

257. The statements contained above were materially false and/or misleading because Defendant Chase misrepresented and failed to disclose the following adverse facts pertaining to the reasons for the growth in Humira's sales and the success of Humira's commercial organization, which were known to Defendants or recklessly disregarded by them. Specifically, Defendant Chase made materially false and/or misleading statements and/or failed to disclose that: (i) AbbVie's strategy to maintain and increase the sales growth of its blockbuster drug, Humira relied in part upon systematic illegal kickbacks and unlawful sales and marketing tactics; (ii) such practices would foreseeably lead to heightened scrutiny by state governments and agencies; and (iii) as a result, Defendant Chase's public statements were materially false and misleading at all relevant times.

258. On January 31, 2014, AbbVie held its Fourth Quarter 2013 Earnings Conference, Call. During the call, Defendant Chase stated, in pertinent part:

> In the US, Humira sales increased 18.1%, reflecting continued market expansion, as well as share gains, particularly in the gastro segment. Internationally, Humira sales grew 8% on an operational basis.
>
> ***
>
> We also expect to see an increase in SG&A as we invest in our key brands, including Humira, where we are pursuing opportunities to further increase penetration rates across indications and drive both disease and brand awareness.

259. The statements contained above were materially false and/or misleading because Defendant Chase misrepresented and failed to disclose the following adverse facts pertaining to the reasons for the growth in Humira's sales and AbbVie's pursuit of increased penetration rates for Humira, which were known to Defendants or recklessly disregarded by them. Specifically, Defendant Chase made materially false and/or misleading statements and/or failed to disclose that: (i) AbbVie's strategy to maintain and increase the sales growth of its blockbuster drug, Humira, relied in part upon systematic illegal kickbacks and unlawful sales and marketing tactics; (ii) such practices would foreseeably lead to heightened scrutiny by state governments and agencies; and (iii) as a result, Defendant Chase's public statements were materially false and misleading at all relevant times.

260. On February 21, 2014, Defendants caused the Company to file with the SEC an annual report for the fiscal year ended December 31, 2013 on Form 10-K (the "2013 10-K"). The 2013 10-K was signed by Defendants Gonzalez and Chase. The 2013 10-K also contained signed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX") by Defendants Gonzalez and Chase attesting to the accuracy of financial reporting, the disclosure of any material changes to the Company's internal controls over financial reporting, and the disclosure of all fraud. Further, Defendants Gonzalez, Alpern, Burnside, Rapp, Tilton, Austin, Liddy, Waddell and Chase signed the 2013 10-K.

261. The 2013 10-K reported the Company's strategic objectives to "drive HUMIRA sales growth[,]":

> ***Strategic Objectives***
>
> AbbVie's long-term strategy is to maximize its existing portfolio of products through new indications, share gains, increased geographic expansion in underserved markets while also advancing its new product pipeline to meet unmet medical needs. To successfully execute its long-term strategy, AbbVie will focus on expanding HUMIRA sales, advancing the pipeline, expanding its presence in emerging markets and managing its product portfolio to maximize value. AbbVie expects to continue to drive strong HUMIRA sales growth in several ways. AbbVie seeks to expand the HUMIRA patient base by applying for regulatory approval of new indications for HUMIRA, treating conditions such as uveitis, hidradenitis suppurativa and pediatric Crohn's disease. AbbVie will also seek to drive HUMIRA sales growth by expanding its market share and its presence in underserved markets.

262. The 2013 10-K also reported that the Company is subject to anti-kickback laws and state laws relating to sales and marketing practices, stating in relevant part:

> ***Laws and regulations affecting government benefit programs could impose new obligations on AbbVie, require it to change its business practices, and restrict its operations in the future.***
>
> The health care industry is subject to various federal, state, and international laws and regulations pertaining to government benefit programs reimbursement, rebates, price reporting and regulation, and health care fraud and abuse. In the United States, these laws include anti-kickback and false claims laws, the Medicaid Rebate Statute, the Veterans Health Care Act, and individual state laws relating to pricing and sales and marketing practices. Violations of these laws may be punishable by criminal and/or civil sanctions, including, in some instances, substantial fines, imprisonment, and exclusion from participation in federal and state health care programs, including Medicare, Medicaid, and Veterans Administration health programs. These laws and regulations are broad in scope and they are subject to change and evolving interpretations, which could require AbbVie to incur substantial costs associated with compliance or to alter one or more of its sales or marketing practices. In addition, violations of these laws, or allegations of such violations, could disrupt AbbVie's business and result in material adverse effect on its business and results of operations.

263. The statements contained above were materially false and/or misleading because Defendants misrepresented and failed to disclose the following adverse facts pertaining to the Company's strategy for expanding Humira's sales, which were known to Defendants or recklessly disregarded by them. Specifically, Defendants made materially false and/or misleading statements and/or failed to disclose that: (i) AbbVie's strategy to maintain and increase the sales growth of its blockbuster drug, Humira, relied in part upon systematic illegal kickbacks and unlawful sales and

marketing tactics; (ii) such practices would foreseeably lead to heightened scrutiny by state governments and agencies; and (iii) as a result, Defendants' public statements were materially false and misleading at all relevant times.

264. The 2013 10-K also described AbbVie's Code of Business Conduct, stating, in pertinent part:

> ***AbbVie's code of business conduct requires all its business activities to be conducted in compliance with laws, regulations, and ethical principles and values***. All directors, officers, and employees of AbbVie are required to read, understand, and ***abide by the requirements of the code of business conduct applicable to them***. AbbVie's code of business conduct is available in the corporate governance section of AbbVie's investor relations website at ww.abbvieinvestor.com.
>
> Any waiver of the code of business conduct for directors or executive officers may be made only by AbbVie's audit committee. ***AbbVie will disclose any amendment to, or waiver from, a provision of the code of conduct for the principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions, on its website within four business days following the date of the amendment or waiver***. In addition, AbbVie will disclose any waiver from the code of business conduct for the other executive officers and for directors on the website. [Emphasis added].

265. The statements contained above were materially false and/or misleading because Defendants misrepresented and failed to disclose that AbbVie was neither in compliance with its Code of Business Conduct, including the requirement that AbbVie conduct its business "in compliance with laws, regulations, and ethical principles and values" nor the requirement that waivers from the Code of Business Conduct be made public, which was known to Defendants or recklessly disregarded by them. Specifically, Defendants made materially false and/or misleading statements and/or failed to disclose that: (i) AbbVie's strategy to maintain and increase the sales growth of its blockbuster drug, Humira, relied in part upon systematic illegal kickbacks and unlawful sales and marketing tactics; (ii) such practices would foreseeably lead to heightened scrutiny by state governments and agencies; and (iii) as a result, Defendants' public statements were materially false and misleading at all relevant times.

266. The disclosures in AbbVie's 2013 10-K concerning its Code of Business Conduct were repeated, in all material respects, in subsequent AbbVie's Forms 10-K and were materially false and misleading when made for the same reasons described above.

267. AbbVie's Code of Business Conduct was mandated by a Corporate Integrity Agreement ("CIA") between the OIG and Abbott, dated May 7, 2012. The CIA was entered into in connection with the settlement of a federal and forty-nine (49) state investigations into improper sales and marketing activities for the drug Depakote, which included $700 million in criminal fines and forfeitures and approximately $900 million to resolve civil claims.

268. Because AbbVie was spun-off as the pharmaceutical arm of Abbott at the time of the CIA, AbbVie assumed "sole responsibility for the terms and obligations of the CIA." Among other things, the CIA required that AbbVie create and maintain the Code of Business Conduct. The Code of Business Conduct recognized that "[v]iolating the Code exposes AbbVie and our people to potential criminal or civil liability and puts our reputation and success at risk."

269. The Code of Business Conduct, which was signed by Defendant Gonzalez and referenced in the Company's 2013 10-K stated, in pertinent part:

> ***We follow all laws and regulations that govern how we work with various governments and their representatives when promoting and selling our product.***
>
> ***We are committed to providing fair, balanced, and accurate information to help patients and their healthcare professionals select the most appropriate treatments.***
>
> Because of the key role healthcare professionals play in determining which products to recommend, prescribe, or use to treat specific diseases or conditions, ***we take special care to avoid even the appearance of unduly influencing their decisions. We promote our products only for uses that have been approved, cleared, or authorized by the relevant government agency.***
>
> ***In interacting with healthcare professionals and other customers, we act with honesty, fairness, and integrity. We follow applicable laws and industry guidelines created to avoid potential conflicts of interest. We never offer or provide anything of value to healthcare professionals or other individuals to inappropriately influence their medical judgment or purchasing or prescribing practices in favor of an AbbVie product. Our commitment to the safety of those who use our products is always at the forefront of everything we do. In order to protect patients, we must***

> ***identify, evaluate, minimize and, whenever possible, eliminate patient safety concerns***.
>
> ***We also comply with all legal and regulatory requirements that govern the reporting of safety information to regulatory or public health agencies*** and communicate with each government agency that oversees our products to address potential safety concerns.
>
> We communicate openly and honestly with healthcare professionals, institutions, patients, and public health agencies ***to ensure that they have the information that they need in order to use AbbVie's products safely and effectively***. We follow up on complaints received about our products in a timely manner and take appropriate corrective actions.
>
> ***None of us should ever, directly or through an intermediary, offer or give anything of value to anyone in order to obtain an improper business advantage***, nor should we ever accept anything of value from a third party in return for preferential treatment.
>
> All of us and our business partners are expected to be aware of ***and follow all anti-corruption and anti-bribery laws*** everywhere we do business.
>
> ***We will not improperly offer, pay, or receive anything of value to obtain business or to influence a business decision. We must be careful not to give any appearance of offering, paying or accepting things of value for a corrupt purpose***. [Emphasis added].

270. The statements contained above were materially false and/or misleading because Defendants misrepresented and failed to disclose that AbbVie was not in compliance with the terms of its Code of Business Conduct, which was known to Defendants or recklessly disregarded by them. Specifically, Defendants made materially false and/or misleading statements and/or failed to disclose that: (i) AbbVie's strategy to maintain and increase the sales growth of its blockbuster drug, Humira, relied in part upon systematic illegal kickbacks and unlawful sales and marketing tactics; (ii) such practices would foreseeably lead to heightened scrutiny by state governments and agencies; and (iii) as a result, Defendants' public statements were materially false and misleading at all relevant times.

271. Apart from the foregoing, during March 2013 and thereafter, the following description of the Company's compliance program appeared on the AbbVie website:

> [The Company] ha[s] policies and procedures that guide employees as they conduct their day-to-day activities. They encompass relevant laws and regulations, including food and drug laws and laws relating to government health care programs.
>
> They also take into account industry best practices, including provisions of the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) Code of Pharmaceutical Marketing Practices, and the Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions with Healthcare Professionals, as well as other applicable industry codes. We regularly update our policies to incorporate changes to the law and industry codes, including rules regarding gifts, meals and education we provide to healthcare professionals.
>
> AbbVie also complies with legal, industry and relevant institutions' requirements regarding the interaction of our employees with health care professionals and organizations. We comply with national, regional, state and other requirements regarding transparency about our relationships with individuals and entities involved in providing health care. As required, we track and report payments and transfers of values (such as meals) provided to health care providers and organizations.

272. These statements were materially false and misleading when made for the same reasons as described above.

273. AbbVie's relevant Forms 10-K each referenced and provided a website link to the Company's Code of Business Conduct, which repeated the same or similar materially false and misleading statements, as described above. The Code of Business Conduct was updated in 2017 and was therefore referenced in AbbVie's Form 10-K for the years ending in 2016 and/or 2017. The 2017 update to the Code of Business Conduct stated, in pertinent part:

> We take care to ensure product information is accurate, comprehensive, relevant and up to date. ***We are fair and open in our dealings with healthcare providers and customers. We do not offer or give gifts or others items or services of value as a means to earn favor for our products or to sway medical judgment.***
>
> ***We comply with all applicable laws that regulate our business***. Many of these laws concern the way we promote and sell our medical products. ***It is never acceptable to try to influence purchasing decisions in any way that is unethical, inappropriate or illegal or create a potential conflict of interest.***
>
> U.S. Anti-Kickback statute. ***We don't give anything of value to induce a healthcare professional to use or recommend pharmaceutical products that are paid for or reimbursed by the government***.

> U.S. False Claims Act and similar laws in other countries. ***We don't submit or cause the submission of false claims for healthcare reimbursement to the government.***
>
> ***We comply with anti-bribery and anti-corruption laws. We do not tolerate improper payments. We understand that accepting, offering or giving anything of value to influence a business decision or gain an unfair business advantage is improper.*** We also understand that improper payments received or given can have severe repercussions for the individuals involved, for AbbVie and ultimately, for our industry and the people we serve. We are careful to maintain accurate books and records to reflect all payments made and received, ***and we avoid even the appearance of anything improper***. [Emphasis added].

274. These statements were materially false and misleading when made for the same reasons as described above.

275. AbbVie's Form 10-K for the years ending in 2016 and/or 2017 and the Code of Business Conduct included in those 10-Ks, were signed by Defendants Gonzalez, Alpern, Burnside Liddy, Tilton, Austin, Hart, Rapp, Waddell, Meyer[12], and Chase.

276. On March 5, 2014, AbbVie presented at the Cowen Health Care Conference. During the presentation, in response to a question from an audience member regarding the competition facing Humira, Defendant Chase had the following exchange:

> Defendant Chase: So the question and I will paraphrase but the question specifically was how do we view SG&A with Humira in that period of time where there is biosimilar competition six to seven years from now?
>
> And I think the reality is one thing we are certain of is biosimilar competition is not going to look like small molecule competition and that is going to result in probably different behaviors with the brands when they lose exclusivity than you would happen to see in a small molecule environment where you are absolutely right the first thing you do is pull away that SG&A resource.
>
> We will want to be out in the market detailing it. That said, I don't think it will require the SG&A investment that you are seeing on the brand right now. ***A lot of what you are seeing on the brand right now is actually driving the growth of the brand. What we have been able to establish over the last couple of years is that Humira is indeed promotionally responsive. And so we have made measured investments for the***

[12] Meyer only signed the 2017 Form 10-K.

brand and they have paid off remarkably well, again 15% growth this past year, probably the fifth or sixth year of $1 billion growth.

And so we are happy with those investments. When you get out in the biosimilar time frame, we are going to be managing the P&L a little differently but that doesn't mean we will pull all support off of the product. Does that help?

Audience Member: Well, you made an interesting comment. When you say the demand is responsive to your marketing investments, what do you attribute that to -- just you are calling on more doctors or (inaudible)?

Defendant Chase: I don't want to get specifically on what our marketing programs are but they are geared primarily at the penetration in the marketplace. Again this is a market that if you look at those patients that would benefit from a biologic even if you go back to rheumatology where we have been competing the longest and the anti-TNF class has been competing the longest, those penetration rates when you look at patients that would benefit from a biologic they are in the high 20%. If you get out to gastro, you are probably talking high single digits, maybe 10%. You get to derm, you are talking 5% to 6% penetration of those patients that would benefit from a biologic. And we are not talking total patients.

And so we see tremendous growth opportunities on the brand just in penetration alone and we have come up with very specific marketing programs that help drive that penetration.

The other nice effect of those marketing programs are we have been able to actually grow Humira quicker than the market. We are taking share and that is really a testament to the strength of the brand, to our marketing execution and to the broad halo of indications that we have. [Emphasis added].

277. The statements contained above were materially false and/or misleading because Defendant Chase misrepresented and failed to disclose that the growth in Humira's sales and the ability of AbbVie's marketing program to maintain and increase the growth of Humira relied, in part, on illegal kickbacks and unlawful sales and marketing tactics, which was known to Defendants or recklessly disregarded by them. Specifically, Defendant Chase made materially false and/or misleading statements and/or failed to disclose that: (i) AbbVie's strategy to maintain and increase the sales growth of its blockbuster drug, Humira, relied in part upon systematic illegal kickbacks and unlawful sales and marketing tactics; (ii) such practices would foreseeably lead to heightened

scrutiny by state governments and agencies; and (iii) as a result, Defendant Chase's public statements were materially false and misleading at all relevant times.

278. On May 8, 2014, the Company filed its quarterly report for the first quarter of 2014 on Form 10-Q (the "Q1 2014 10-Q") with the SEC, which provided the Company's quarterly financial results and position. The Q1 2014 10-Q was signed by Defendants Gonzalez and Chase.

279. The Q1 2014 10-Q enumerated the drivers of Humira's sales growth in the quarter, stating, in pertinent part:

> On a constant currency basis, global HUMIRA sales increased 18 percent ***primarily as a result of continued market growth across therapeutic categories and geographies, higher market share and higher pricing in certain geographies.*** In the United States, HUMIRA sales continued to expand across therapeutic categories. Internationally, growth is driven by the continued uptake of new indications, increased market share and market growth in most key countries. AbbVie is pursuing several new indications to help further differentiate from competitive products and add to the sustainability and future growth of HUMIRA. [Emphasis added].

280. The statement contained above was materially false and/or misleading because Defendants misrepresented and failed to disclose that the growth of Humira sales relied, in part on illegal kickbacks and unlawful sales and marketing tactics, which was known to Defendants or recklessly disregarded by them. Specifically, Defendants made a materially false and/or misleading statement and/or failed to disclose that: (i) AbbVie's strategy to maintain and increase the sales growth of its blockbuster drug, Humira, relied in part upon systematic illegal kickbacks and unlawful sales and marketing tactics; (ii) such practices would foreseeably lead to heightened scrutiny by state governments and agencies; and (iii) as a result, Defendants' public statement was materially false and misleading at all relevant times.

281. The statement contained above alleged to be materially false and misleading concerning the quarterly growth of Humira's sales was repeated, in all material respects, in AbbVie's Forms 10-Q filed on August 7, 2014 and November 7, 2014 and was materially false and misleading when made.

282. On May 15, 2014, AbbVie presented at the Bank of America Merrill Lynch Health Care Conference. During the presentation, in response to a question from Bank of America analyst Colin Bristow regarding the drivers of Humira's growth, Defendant Chase stated in pertinent part:

> It is an extraordinary brand and we feel that if you had to have a pharmaceutical asset, this is the one you want. I mean the growth potential of this brand, as well as the growth that it's delivered over the last few years, this is a brand that has increasing sales over the last five years at about $1 billion, over $1 billion per year. And it is absolutely -- it is a remarkable product.
>
> ***How does that happen? Well, first of all, it stems directly from the compelling benefits that Humira offers both patients and payers, but then specifically the growth drivers begin with the fact that, if you look at the markets that Humira is applicable in, the autoimmune markets, whether it is rheum, gastro, derm, the reality is the penetration of biologics versus the total population that would benefit from biologics, it is still quite low, even with the fact that anti-TNFs have been out for -- since the beginning of the decade.*** In rheumatology, you are probably talking a penetration rate of 20%, 25%. You go down to derm, we are talking 5%, 6%, highly, highly underpenetrated markets when you compare it to the population of patients who would benefit from the therapy. ***So that is a huge driver. And that is the primary driver.***
>
> ***That said, the benefits that Humira brings and the comfort that physicians have with Humira and its strong safety record are such that actually Humira is picking up share in these markets and that is our second growth driver.*** The third growth driver is new indications. Scott can certainly tell you about the additional indications we are pursuing, but even without those, we have the broadest aura of indications of any anti-TNF out there.
>
> ***And then finally there is an interesting geographic play to the brand given that if you move outside of the developed market, those penetration rates are still yet lower than what we see in the developed markets and so there is, in a way, a geographic expansion story for Humira as well. You add those four drivers up and you see the performance we have been putting up on the brand.*** [Emphasis added].

283. The statements contained above were materially false and/or misleading because Defendant Chase misrepresented and failed to disclose that a "driver" of Humira's sales growth and market share included illegal kickbacks and unlawful sales and marketing tactics, which were known to Defendants or recklessly disregarded by them. Specifically, Defendant Chase made materially false and/or misleading statements and/or failed to disclose that: (i) AbbVie's strategy to

maintain and increase the sales growth of its blockbuster drug, Humira, relied in part upon systematic illegal kickbacks and unlawful sales and marketing tactics; (ii) such practices would foreseeably lead to heightened scrutiny by state governments and agencies; and (iii) as a result, Defendant Chase's public statements were materially false and misleading at all relevant times.

284. On June 11, 2014, AbbVie presented at the Goldman Sachs Healthcare Conference. During the presentation, in response to a question by Goldman Sachs analyst Jami Rubin on investment spending, Defendant Chase described AbbVie's promotional spending for Humira and its effect on Humira's growth, stating, in pertinent part:

> So, let me answer it on both an absolute and a profile standpoint. On an absolute basis, we already have the bulk of our launch for HCV built into our P&L. We certainly will have to go and look at launch requirements for products like 199, daclizumab, elagolix -- other compounds. We're going to fund those.
>
> ***That said, when you look at the top line growth -- and additionally, we have shown, I think, very, very compellingly in 2013 and 2014, that Humira itself is promotional-responsive. And what we're going to do is, we're going to make sure that we invest appropriately in Humira to continue the growth in that brand***. [Emphasis added].

285. The statements contained above were materially false and/or misleading because Defendant Chase misrepresented and failed to disclose that AbbVie's promotion of Humira, and the resulting sales growth, relied, in part, on illegal kickbacks and unlawful sales and marketing tactics, which was known to Defendants or recklessly disregarded by them. Specifically, Defendant Chase made materially false and/or misleading statements and/or failed to disclose that: (i) AbbVie's strategy to maintain and increase the sales growth of its blockbuster drug, Humira, relied in part upon systematic illegal kickbacks and unlawful sales and marketing tactics; (ii) such practices would foreseeably lead to heightened scrutiny by state governments and agencies; and (iii) as a result, Defendant Chase's public statements were materially false and misleading at all relevant times.

286. On June 25, 2014, AbbVie held a conference call to discuss a possible combination with Shire plc. During the conference call, in response to a question from Cowen and Company

analyst Steve Scala regarding Defendants' long term view on Humira, Defendant Gonzalez discussed AbbVie's strategy for maintaining and growing Humira's sales, stating in pertinent part:

> As far as Humira is concerned, we have talked many, many times publicly about our views of Humira and our ability to be able to protect and grow Humira. And as I indicated in my interim -- my remarks today, we have put in a very robust strategy to protect Humira from an IP standpoint, to enhance Humira, to make it even more appealing for patients and give patients more benefit.

287. The statements contained above were materially false and/or misleading because Defendant Gonzalez misrepresented and failed to disclose that AbbVie's strategy to maintain and grow Humira sales included illegal kickbacks and unlawful sales and marketing tactics, which was known to Defendants or recklessly disregarded by them. Specifically, Defendant Gonzalez made materially false and/or misleading statements and/or failed to disclose that: (i) AbbVie's strategy to maintain and increase the sales growth of its blockbuster drug, Humira, relied in part upon systematic illegal kickbacks and unlawful sales and marketing tactics; (ii) such practices would foreseeably lead to heightened scrutiny by state governments and agencies; and (iii) as a result, Defendant Gonzalez's public statements were materially false and misleading at all relevant times.

288. On July 25, 2014, AbbVie held its Second Quarter 2014 Earnings Call. During the call, Defendant Chase reported on the drivers of Humira's sales growth, stating, in pertinent part: Humira delivered global sales of nearly $3.3 billion, up 25.4% on an operational basis and 26.2% on a reported basis. In the United States, Humira sales increased 35.6%, driven by continued market expansion, share gains, and particularly strong growth in the gastro segment. Growth in the second quarter also benefited from retail buying patterns and a favorable comparison to the prior year.

289. The statements contained above were materially false and/or misleading because Defendant Chase misrepresented and failed to disclose that Humira's sales growth was driven, in part, by illegal kickbacks and unlawful sales and marketing tactics, which was known to Defendants or recklessly disregarded by them. Specifically, Defendant Chase made materially false and/or misleading statements and/or failed to disclose that: (i) AbbVie's strategy to maintain and increase the sales growth of its blockbuster drug, Humira, relied in part upon systematic illegal kickbacks

and unlawful sales and marketing tactics; (ii) such practices would foreseeably lead to heightened scrutiny by state governments and agencies; and (iii) as a result, Defendant Chase's public statements were materially false and misleading at all relevant times.

290. On August 7, 2014, the Company filed its quarterly report for the second quarter of 2014 on Form 10-Q (the "Q2 2014 10-Q") with the SEC, which provided the Company's quarterly financial results and position. The Q2 2014 10-Q was signed by Defendants Gonzalez and Chase.

291. The Q2 2014 10-Q enumerated the drivers of Humira's sales growth in the quarters stating, in pertinent part:

> On a constant currency basis, global HUMIRA sales increased 25 percent and 22 percent during the three and six months ended June 30, 2014, respectively, ***primarily as a result of continued market growth across therapeutic categories and geographies, higher market share and higher pricing in certain geographies. In the United States, HUMIRA sales were driven by continued market expansion, market share gains and growth across therapeutic categories, gastroenterology in particular, and higher pricing. Sales also benefitted from retail buying patterns and a favorable comparison to the prior year, particularly for the three months ended June 30, 2014***. Wholesaler inventory levels remained at approximately two weeks, consistent with the first three months of 2014. Internationally, growth is driven by the continued growth in new indications, increased market share and market growth in most key countries. AbbVie in pursuing several new indications to help further differentiate from competitive products and add to the sustainability and future growth of HUMIRA. [Emphasis added].

292. The statements contained above were materially false and/or misleading because Defendants misrepresented and failed to disclose that the drivers of Humira's sales growth included illegal kickbacks and unlawful sales and marketing tactics, which was known to Defendants or recklessly disregarded by them. Specifically, Defendants made materially false and/or misleading statements and/or failed to disclose that: (i) AbbVie's strategy to maintain and increase the sales growth of its blockbuster drug, Humira, relied in part upon systematic illegal kickbacks and unlawful sales and marketing tactics; (ii) such practices would foreseeably lead to heightened scrutiny by state governments and agencies; and (iii) as a result, Defendants' public statements were materially false and misleading at all relevant times.

293. On September 10, 2014, AbbVie presented at the Morgan Stanley Healthcare Conference. During the presentation, Morgan Stanley analyst David Risinger asked Defendant Chase a question regarding the "ongoing Humira growth drivers." Defendant Chase responded, stating in pertinent part:

> Yes. Humira is an incredible, incredible product. And when married with the team that supports it, you've seen -- as well as prudent investment, you've seen just what the product can do. Our second quarter growth rates were absolutely phenomenal, both in the US and abroad. And we continue to forecast strong growth from the product.
>
> ***The key drivers of that growth start with the fact that, in the autoimmune segments that Humira participates in, anti-TNF penetration is actually surprisingly low***. And so, if you look at rheumatology, penetration of patients that would benefit from a biologic is probably in the high 20%'s, and much lower when you get into GI, and still lower yet with dermatology where you see about 6% to 7% penetration rates.
>
> So, there's still profound opportunities for penetration. ***We continue to gain share on our competitors, so that's a growth driver.*** We have an active program in place to continue to expand our indications for Humira. It's already the most broadly indicated anti-TNF, but we're continuing to work on new and exciting indications.
>
> ***And then, if you move outside of the developed markets, those penetration rates are still yet lower. And so, there is a pretty impressive geographic expansion story behind Humira as well***.
>
> ***So, those are four very, very powerful growth drivers***. You can certainly see what they've contributed to the brand over the last five to six years. And we remain very, very bullish on the brand going into 2015, 2016, and beyond. [Emphasis added].

294. The statements contained above were materially false and/or misleading because Defendant Chase misrepresented and failed to disclose that the growth of Humira's sales and penetration rates were driven, in part, by illegal kickbacks and unlawful sales and marketing tactics, which was known to Defendants or recklessly disregarded by them. Specifically, Defendant Chase made materially false and/or misleading statements and/or failed to disclose that: (i) AbbVie's strategy to maintain and increase the sales growth of its blockbuster drug, Humira, relied in part upon systematic illegal kickbacks and unlawful sales and marketing tactics; (ii) such practices would foreseeably lead to heightened scrutiny by state governments and agencies; and (iii) as a

result, Defendant Chase's public statements were materially false and misleading at all relevant times.

295. On October 20, 2014, AbbVie held a conference call regarding the termination of the Shire plc transaction. During the call, Defendants Gonzalez discussed the growth drivers for Humira, stating, in pertinent part:

> Our fundamental strategy is strong, and ***we have built an excellent foundation. As a result, AbbVie is now poised to deliver top-tier performance through multiple growth drivers. We expect continued growth from our flagship product, Humira, driven by market expansion, share gains and new indications***. We believe Humira will generate strong revenues for many years to come. [Emphasis added].

296. The statements contained above were materially false and/or misleading because Defendant Gonzalez misrepresented and failed to disclose that Humira's sales growth was driven, in part, by illegal kickbacks and unlawful sales and marketing tactics, which was known to Defendants or recklessly disregarded by them. Specifically, Defendant Gonzalez made materially false and/or misleading statements and/or failed to disclose that: (i) AbbVie's strategy to maintain and increase the sales growth of its blockbuster drug, Humira, relied in part upon systematic illegal kickbacks and unlawful sales and marketing tactics; (ii) such practices would foreseeably lead to heightened scrutiny by state governments and agencies; and (iii) as a result, Defendant Gonzalez's public statements were materially false and misleading at all relevant times.

297. On October 31, 2014, AbbVie held its Third Quarter 2014 Earnings Call. During the call Defendant Gonzalez discussed Humira's sales growth for the quarter. Defendant Gonzalez stated, in pertinent part:

> Our third-quarter results were led by Humira, which delivered nearly 18% global operational growth. ***Humira's performance was driven by several factors including continued market growth resulting from increasing penetration across therapeutic categories and geographies.*** As we've indicated in the past, Humira's broad label and new indications are a competitive advantage. [Emphasis added].

298. On the call, Defendant Chase also discussed Humira's growth drivers in the third quarter, stating, in pertinent part:

> Humira delivered global sales of more than $3.2 billion, up 17.8% operationally and up 17.5% on a reported basis. ***In the United States Humira sales increased 25.3% driven by continued market expansion, strong prescription trends and share gains partially offset by a reduction in retail buying patterns***. Internationally, Humira sales grew 10.3% on an operational basis excluding a 0.6% unfavorable impact from exchange. [Emphasis added].

299. During the question and answer portion of the Third Quarter 2014 Earnings Call, Goldman Sachs analyst Jami Rubin asked a question regarding expected 2015 earnings growth for Humira. In response, Defendant Gonzalez stated in pertinent part:

> And so we've obviously modeled what that looks like and I can tell you we have confidence in what we can do in that area. I'm not going to give you a lot more specifics on that at this point. ***We've described in detail what it looks like, that is a combination of three major areas: product enhancements, both formulation as well as device, intellectual property and commercial strategies***. [Emphasis added].

300. The statements contained above were materially false and/or misleading because Defendants Gonzalez and Chase misrepresented and failed to disclose that Humira's sales growth was driven, and would continue to be driven, in part, by illegal kickbacks and unlawful sales and marketing tactics, which was known to Defendants or recklessly disregarded by them. Specifically, Defendants Gonzalez and Chase made materially false and/or misleading statements and/or failed to disclose that: (i) AbbVie's strategy to maintain and increase the sales growth of its blockbuster drug, Humira, relied in part upon systematic illegal kickbacks and unlawful sales and marketing tactics; (ii) such practices would foreseeably lead to heightened scrutiny by state governments and agencies; and (iii) as a result, the public statements of Defendants Gonzalez and Chase were materially false and misleading at all relevant times.

301. On November 20, 2014, AbbVie presented at the Jefferies Global Healthcare Conference. During the presentation, Jefferies analyst Jeff Holford asked a question concerning, the reasons for Humira's performance in the second and third quarters of 2014. Defendant Chase responded, stating, in pertinent part:

> Well, obviously, let's start with Humira because that is a huge part of the business. Humira has just been performing outstandingly. If you really look at it, we came into the year guiding double-digit growth, which we thought was appropriate. If you look

> at the TRX trends in Q3 in the US for example, we had a 14% TRX growth and I think what that speaks to is a number of different things. ***Clearly, this is a market that's underpenetrated by biologics and there's a lot of patients out there that would be well-served and that's been driving market growth and we've expected to see that and we've enjoyed that.*** But I think what you're seeing on top of it is just how compelling Humira is as a brand and how our execution is on the marketing front. And we're just very, very pleased with the progress. [Emphasis added].

302. The statement contained above was materially false and/or misleading because Defendant Chase misrepresented and failed to disclose that Humira's sales growth was driven "on the marketing front," in part, by illegal kickbacks and unlawful sales and marketing tactics, which was known to Defendants or recklessly disregarded by them. Specifically, Defendant Chase made a materially false and/or misleading statement and/or failed to disclose that: (i) AbbVie's strategy to maintain and increase the sales growth of its blockbuster drug, Humira, relied in part upon systematic illegal kickbacks and unlawful sales and marketing tactics; (ii) such practices would foreseeably lead to heightened scrutiny by state governments and agencies; and (iii) as a result, Defendant Chase's public statement was materially false and misleading at all relevant times.

303. On January 6, 2015, AbbVie participated in the Goldman Sachs CEOs Unscripted Healthcare Conference. During a question and answer session, Goldman Sachs analyst Jami Rubin asked about AbbVie's longer-term growth outlook. In response, Defendant Gonzalez discussed AbbVie's strategy, stating, in pertinent part:

> Obviously, the second part of that is how we deal with biosimilar competition if and when it comes. And that's an area we've been working on and planning for for an extended period of time. ***We have put in place what we believe is a robust strategy to manage that.*** And it obviously consists of really four key elements.
>
> One is we have a robust portfolio of intellectual property that covers both process patents, manufacturing patents, method of use patents, and a number of other areas.
>
> And we think that will be an important part of our overall strategy. In addition to that, we are in the process of making enhancements to HUMIRA, both formulation enhancements as well as device enhancements, to further differentiate the product. And we think that will be an important set of enhancements that will allow us to differentiate ourselves versus any biosimilars.

> ***Our commercial strategy will play an important role in how we deal with biosimilar competitors.*** And then finally, we've obviously been working on an immunology pipeline to develop additional assets beyond HUMIRA which can continue to drive our leadership position in those categories.
>
> And so when I stepped back and I look at that strategy, I feel confident that we can manage effectively the biosimilar impact that would occur in that timeframe. And we are clearly committed to being able to drive strong performance in that window. [Emphasis added].

304. The statements contained above were materially false and/or misleading because Defendant Gonzalez misrepresented and failed to disclose that AbbVie's commercial strategy for maintaining and increasing Humira's sales growth included illegal kickbacks and unlawful sales and marketing tactics, which was known to Defendants or recklessly disregarded by them. Specifically, Defendant Gonzalez made materially false and/or misleading statements and/or failed to disclose that: (i) AbbVie's strategy to maintain and increase the sales growth of its blockbuster drug, Humira, relied in part upon systematic illegal kickbacks and unlawful sales and marketing tactics; (ii) such practices would foreseeably lead to heightened scrutiny by state governments and agencies; and (iii) as a result, Defendant Gonzalez's public statements were materially false and misleading at all relevant times.

305. On January 14, 2015, AbbVie presented at the JPMorgan Healthcare Conference. During the presentation, Defendant Chase discussed Humira's 2015 growth outlook, stating, in pertinent part:

> As we plan for 2015, we expect Humira to be an important contributor to our robust growth. Humira has delivered significant annual growth in recent years and it has several unique attributes that we believe will help it to continue to grow in the years to come.
>
> One of these attributes, of course, is Humira's broad and growing list of approved indications. In 2014, we completed our clinical program evaluating Humira as a treatment for HS, a chronic inflammatory skin disease. We reported positive results from two Phase III studies and our US and EU regulatory applications are currently under review. Given disease prevalence and the lack of effective treatment options, we believe HS has the potential to be a meaningful indication with peak year sales that could approach $1 billion.

> We're also exploring Humira as a possible treatment for uveitis, a sight threatening inflammatory eye disease. We expect to complete a Phase III program and submit our regulatory applications for uveitis later this year.
>
> Other factors that have driven strong Humira growth to date are expected to continue as well, including robust underlying demand resulting from increased penetration, market share gains and further geographic expansion. 2014 was another stellar year for our flagship product and the dynamics are favorable for continued growth and cash flow generation in 2015 and in the years to come.

306. The statements contained above were materially false and/or misleading because Defendant Chase misrepresented and failed to disclose that Humira's sales growth and penetration was driven, in part, by illegal kickbacks and unlawful sales and marketing tactics, which was known to Defendants or recklessly disregarded by them. Specifically, Defendant Chase made materially false and/or misleading statements and/or failed to disclose that: (i) AbbVie's strategy to maintain and increase the sales growth of its blockbuster drug, Humira, relied in part upon systematic illegal kickbacks and unlawful sales and marketing tactics; (ii) such practices would foreseeably lead to heightened scrutiny by state governments and agencies; and (iii) as a result, Defendant Chase's public statements were materially false and misleading at all relevant times.

307. On February 20, 2015, Defendants caused the Company to file with the SEC an annual report for the fiscal year ended December 31, 2014 on Form 10-K (the "2014 10-K"). The 2014 10-K was signed by Defendants Gonzalez and Chase. The 2014 10-K also contained signed SOX certifications by Defendants Gonzalez and Chase attesting to the accuracy of financial reporting, the disclosure of any material changes to the Company's internal controls over financial reporting, and the disclosure of all fraud. Further, Defendants Gonzalez, Alpern, Burnside, Rapp, Tilton, Austin, Liddy, Waddell, Chase, and non-party Roberts all signed the 2014 10-K.

308. The 2014 10-K enumerated the Company's strategic objectives for 2015 to "continue to drive strong HUMIRA sales growth[,]":

> ***2015 Strategic Objectives***
>
> In 2015, AbbVie expects sales performance to be driven by continued strong growth from HUMIRA, the launch of VIEKIRA PAK, and sales growth in certain key

> products including Creon and Duodopa, partially offset by a decline in several products due to generic competition, including AndroGel 1% and the remainder of the lipid franchise. In addition, AbbVie expects to achieve operating margin improvements while continuing to invest in its pipeline in support of opportunities in oncology, HCV, and immunology, as well as continued investment in key products. AbbVie expects to grow operating cash flows in 2015, which will enable the company to continue to augment its pipeline through concerted focus on strategic licensing, acquisition and partnering activity and returning cash to shareholders via dividends and share repurchases. AbbVie expects to continue to drive strong HUMIRA sales growth in several ways. AbbVie seeks to expand the HUMIRA patient base by applying for regulatory approval of new indications for HUMIRA, treating conditions such as uveitis and hidradenitis suppurativa. AbbVie will also seek to drive HUMIRA sales growth by expanding its market share and its presence in underserved markets. AbbVie plans to continue making investments in key emerging markets, including Brazil, China, and Russia.

309. The 2014 10-K also stated the Company is subject to anti-kickback laws and state laws relating to sales and marketing practices:

> ***Laws and regulations affecting government benefit programs could impose new obligations on AbbVie, require it to change its business practices, and restrict its operations in the future***.
>
> The health care industry is subject to various federal, state, and international laws and regulations pertaining to government benefit programs reimbursement, rebates, price reporting and regulation, and health care fraud and abuse. In the United States, these laws include anti-kickback and false claims laws, the Medicaid Rebate Statute, the Veterans Health Care Act, and individual state laws relating to pricing and sales and marketing practices. Violations of these laws may be punishable by criminal and/or civil sanctions, including, in some instances, substantial fines, imprisonment, and exclusion from participation in federal and state health care programs, including Medicare, Medicaid, and Veterans Administration health programs. These laws and regulations are broad in scope and they are subject to change and evolving interpretations, which could require AbbVie to incur substantial costs associated with compliance or to alter one or more of its sales or marketing practices. In addition, violations of these laws, or allegations of such violations, could disrupt AbbVie's business and result in a material adverse effect on its business and results of operations.

310. On March 5, 2015, AbbVie held a conference call to discuss the Company's acquisition of Pharmacyclics. During the call, Defendant Gonzalez discussed AbbVie's strategy to continue to grow Humira sales, stating, in pertinent part:

> Clearly we have a strong leadership position in the immunology market with Humira, the world's leading anti-TNF; ***and we have a multifaceted strategy in place which we believe will allow us to protect and grow our position.*** Humira has averaged well over $1 billion of growth per year over the past eight years, and it has many unique attributes that will help it continue to grow in the years to come. [Emphasis added].

311. The statement contained above was materially false and/or misleading because Defendant Gonzalez misrepresented and failed to disclose that AbbVie's strategy to maintain and grow Humira's sales was driven, in part, by illegal kickbacks and unlawful sales and marketing tactics, which was known to Defendants or recklessly disregarded by them. Specifically, Defendant Gonzalez made a materially false and/or misleading statement and/or failed to disclose that: (i) AbbVie's strategy to maintain and increase the sales growth of its blockbuster drug, Humira, relied in part upon systematic illegal kickbacks and unlawful sales and marketing tactics; (ii) such practices would foreseeably lead to heightened scrutiny by state governments and agencies; and (iii) as a result, Defendant Gonzalez's public statement was materially false and misleading at all relevant times.

312. On April 23, 2015, AbbVie held its First Quarter 2015 Earnings Call. During that call, Defendant Gonzalez discussed the Company's strategy for driving Humira sales, stating, in pertinent part:

> As we have said, we expect HUMIRA to continue to drive strong growth and significant cash flow generation for many years. ***We have a multifaceted strategy in place, which we believe will allow us to protect and grow our immunology position***. We have two new indications in late-stage develop, as well as a new formulation currently under regulatory review in the US and in Europe. [Emphasis added].

313. During the question and answer portion of the call, Defendant Chase responded to a question from Evercore analyst Mark Schoenbaum regarding AbbVie's long range plans, stating in pertinent part:

> Now, let's take the opposite example of that, HUMIRA. HUMIRA is a complex business model. HUMIRA sales and profit contributions come from a broad geographic footprint, with about 40% of its sales coming from outside the United States. ***HUMIRA has an unparalleled breadth of indications and we use a unique selling model for HUMIRA. We utilize specialized and dedicated sales***

> ***organizations for all major indications. We manage and invest in HUMIRA to maximize its short- and its long-term value to the Company and to our shareholders***.
>
> I think it's pretty hard to argue with our success. When we took the Company public a little over two years ago, HUMIRA was a $9 billion product. Today, in 2015, HUMIRA is a $14 billion product. $5 billion of growth in 2.5 years, despite the foreign exchange headwinds. The brand is 55% larger. [Emphasis added].

314. The statements contained above were materially false and/or misleading because Defendants Gonzalez and Chase misrepresented and failed to disclose that Humira's sales growth and "selling model" were driven, in part, by illegal kickbacks and unlawful sales and marketing tactics, which was known to Defendants or recklessly disregarded by them. Specifically, Defendants Gonzalez and Chase made materially false and/or misleading statements and/or failed to disclose that: (i) AbbVie's strategy to maintain and increase the sales growth of its blockbuster drug, Humira, relied in part upon systematic illegal kickbacks and unlawful sales and marketing tactics; (ii) such practices would foreseeably lead to heightened scrutiny by state governments and agencies; and (iii) as a result, the public statements of Defendants Gonzalez and Chase were materially false and misleading at all relevant times.

315. On May 6, 2015, AbbVie presented at the Deutsche Bank Health Care Conference. During the presentation, Deutsche Bank analyst Robyn Karnauskas asked a question regarding AbbVie's Selling, General and Administrative expenses for supporting Humira's sales. In response, Defendant Chase or AbbVie Vice President of Pharmaceutical Development Scott Brun ("Brun") responded, stating, in pertinent part:

> Well the first thing you got to ask is what is the decline curve on HUMIRA, right? In the extent that there our theses is right and that's a relatively moderate decline and that we're continuing to capture patients. You know that SG&A is valuable SG&A. ***The SG&A that we built out on HUMIRA, we made a purposeful decision in 2012 -- end of 2012, 2013 somewhat in 2014 to invest in HUMIRA, because we knew with our preferred payer position as well as the fact that we were gaining the majority of new patients we knew that if we could deploy SG&A in an effort to drive penetration and get biologics into the hands of those patients that needed biologics, forget about branding, we were going to pick up an unfair share of the patients as a result. And it was just that simple. We saw the net, if you will, being built downstream between our preferred position and the fact that the brand itself had a very, very strong capture rate of new patients and we realized that if we could put specific programs***

> ***in place that would drive getting biologics into the right patients, decreasing the amount of time it took to get a biologic in the hands of that patient, compliance programs, et cetera, we could actually grow the market and that's why you've seen acceleration in HUMIRA*** script volumes despite the age and size of the brand and it's really just that simple. So that's productive SG&A and we love that investment. [Emphasis added].

316. The statements contained above were materially false and/or misleading because Defendant Chase or Brun misrepresented and failed to disclose that AbbVie's strategy and "specific programs" to maintain and increase Humira sales and market penetration included illegal kickbacks and unlawful sales and marketing tactics, which was known to Defendants or recklessly disregarded by them. Specifically, Defendant Chase or Brun made materially false and/or misleading statements and/or failed to disclose that: (i) AbbVie's strategy to maintain and increase the sales growth of its blockbuster drug, Humira, relied in part upon systematic illegal kickbacks and unlawful sales and marketing tactics; (ii) such practices would foreseeably lead to heightened scrutiny by state governments and agencies; and (iii) as a result, the public statements of Defendant Chase or Brun were materially false and misleading at all relevant times.

317. On May 8, 2015, the Company filed its quarterly report for the first quarter of 2015 on Form 10-Q (the "Q1 2015 10-Q") with the SEC, which provided the Company's quarterly financial results and position. The Q1 2015 10-Q was signed by Defendants Gonzalez and Chase.

318. The Q1 2015 10-Q enumerated the drivers of Humira's sales growth in the quarter, stating, in pertinent part:

> Global HUMIRA sales increased 26 percent on a constant currency basis during the three months ended March 31, 2015, ***primarily as a result of market growth across therapeutic categories and geographies, higher market share, and favorable pricing in certain geographies***. AbbVie continues to pursue several new indications to help further differentiate HUMIRA from competing products and add to the sustainability and future growth of HUMIRA. [Emphasis added].

319. The statement contained above was materially false and/or misleading because Defendants misrepresented and failed to disclose that the growth of Humira sales relied, in part, on illegal kickbacks and unlawful sales and marketing tactics, which was known to Defendants or recklessly disregarded by them. Specifically, Defendants made a materially false and/or misleading

statement and/or failed to disclose that: (i) AbbVie's strategy to maintain and increase the sales growth of its blockbuster drug, Humira, relied in part upon systematic illegal kickbacks and unlawful sales and marketing tactics; (iii) such practices would foreseeably lead to heightened scrutiny by state governments and agencies; and (iii) as a result, Defendants' public statement was materially false and misleading at all relevant times.

320. On May 13, 2015, AbbVie presented at the Bank of America Merrill Lynch Health Care Conference. During that presentation, Bank of America analyst Colin Bristow asked a question regarding AbbVie's strategy for addressing biosimilar competition for Humira. Defendant Gonzalez responded, stating, in pertinent part:

> ***We have a multi-facetted strategy to protect or grow our position in immunology and it's comprised of our portfolio of intellectual property that we believe will protect the asset enhancements that we will make with HUMIRA formulation device enhancements, the commercial strategy we will put in place and then obviously launching new assets into this category like the JAKs, like ABT-122 or dual variable domain antibody or DVD that has an IL-17 and TNF on it to be able to grow those assets going forward***.
>
> ***
>
> And so, that's the strategy we use on our solids, that's what we used with TriCor and TRILIPIX and Niaspan and we're doing some of that right now with AndroGel as an example. But in case of biosimilars, it's a very different situation. So at the point at which we assume, we could see biosimilar competition in the marketplace, the strategy we have in place now is one where we titrate the expenses down in that country. ***But ultimately, we have a strategy that we believe will sustain our position in that market.*** But then, we have a contingency plan ourselves. If for whatever reason within that country, it doesn't go the way we thought it would go and we start to see erosion occurring more rapidly than we expected, we are in a position to be able to take resources down correspondingly, but we don't want to do it like we do in small molecules ahead of the event because you might pre- determine your fate in that example and we certainly don't want to do that in this example. [Emphasis added].

321. Defendant Gonzalez then provided further detail regarding AbbVie's strategy, stating in pertinent part:

> I think we have articulated clearly how we're thinking about the various spaces of biosimilar competition, and it really starts with how do we believe HUMIRA will

behave in an indirect biosimilar environment. We've seen now playing out in the international markets for the last couple of years, and I would say our operating assumption when we went into that was that HUMIRA would not be negatively impacted by indirect biosimilar competition. We continue to monitor every single country, whether you look at them in aggregate or you look at them individually, HUMIRA continues to gain patient share on a constant dollar basis -- continues to grow constant dollars share as well. And so, indeed it is performing within the range of what we expected. I'd also say the pricing is within the range of what we expected to discount, it's in the range of what we expected for the biosimilars. But we continue to study about the competitive response and the biosimilars response in each of those marketplaces. So that's kind of the first phase.

***

So you are going to see all of that play out as someone moves forward with an application in the US. And so as we lay all of that out we have made a set of assumptions as to when we would likely see biosimilar competition, many of those patents have expirations that are out in the 2022 to 2026 patent range themselves. So if we prevail in that litigation, obviously, those patents will be upheld through that period of time. So that's the first phase of the strategy. Then the second phase will be the new formulations and new devices and then at that point, if there is a biosimilar, they maybe the predominant formulation in the marketplace. ***And then there is the commercial strategy and are in the United States in particular, our position in managed care***, and then ultimately it would be the assets that we have in development now, giving them into the marketplace and starting to grow on top of HUMIRA. We believe those assets, the target product profile that we have for those assets will allow us to reinstate standard of care in some of these areas. And if we get those launched and in the marketplace where we can be up the ramp of those assets, then obviously any erosion that we would see on biosimilars, we would be hopeful that we can offset or even grow above that with those other assets. So that's the fundamental strategy that we've put in place and thus far, it is tracking the way we assume. [Emphasis added].

322. The statements contained above were materially false and/or misleading because Defendant Gonzalez misrepresented and failed to disclose that AbbVie's strategy to maintain Humira sales included illegal kickbacks and unlawful sales and marketing tactics, which was known to Defendants or recklessly disregarded by them. Specifically, Defendant Gonzalez made materially false and/or misleading statements and/or failed to disclose that: (i) AbbVie's strategy to maintain and increase the sales growth of its blockbuster drug, Humira, relied in part upon systematic illegal kickbacks and unlawful sales and marketing tactics; (ii) such practices would

foreseeably lead to heightened scrutiny by state governments and agencies; and (iii) as a result, Defendant Gonzalez's public statements were materially false and misleading at all relevant times.

323. On May 20, 2015, AbbVie presented at the UBS Global Healthcare Conference. During the presentation, UBS analyst Marc Goodman asked a question regarding AbbVie's plan for addressing a biosimilar that competes with Humira. Defendant Chase responded by discussing AbbVie's strategy, stating in pertinent part:

> Eventually, though, there will be a biosimilar that makes it to market, ***and that's where the commercial strategy comes into play. And if you look at our position in the US, for example, with payers, we are now the preferred anti-TNF agent in well over 80% of the lives. That preferred position is supported by a rebate stream. We think it's going to be difficult for a biosimilar competitor to actually challenge us within a payer environment purely on price, which will be really their only advantage, given that in this space it's not good therapy to be taking a patient and actively switching it to an alternate anti-TNF. You run the risk of throwing a patient out of remission, at which point that adds cost, it's not good for the patient, etc. So, when we look at how the battle will play out commercially with the payers, we think it is much more likely that there will be some price concessions, but that we will hold a dominant position within those specific payers, and that you will not see a small molecule decline, if you will, play out when a biosimilar enters***. [Emphasis added].

324. The statements contained above were materially false and/or misleading because Defendant Chase misrepresented and failed to disclose that AbbVie's strategy to maintain Humira sales and market share included illegal kickbacks and unlawful sales and marketing tactics, which was known to Defendants or recklessly disregarded by them. Specifically, Defendant Chase made materially false and/or misleading statements and/or failed to disclose that: (i) AbbVie's strategy to maintain and increase the sales growth of its blockbuster drug, Humira, relied in part upon systematic illegal kickbacks and unlawful sales and marketing tactics; (ii) such practices would foreseeably lead to heightened scrutiny by state governments and agencies; and (iii) as a result, Defendant Chase's public statements were materially false and misleading at all relevant times.

325. On June 4, 2015, AbbVie presented at the Jefferies Global Healthcare Conference. During the presentation, Jefferies analyst Jeff Holford asked a question concerning how AbbVie

had dealt with competitive pressure in the market for Humira. Defendant Gonzalez responded, discussing Humira's growth in the following exchange:

> **Jeff Holford**: Okay, that's great. I just wanted to get back to you, Rick, and maybe Bill as well, if you want to jump in on this. So I think what a lot of people do forget about once we do see a biosimilar environment is that they've seen the (inaudible) markets actually being very competitive for a very long time with multiple comparable products in it. And I just wonder if you have any good anecdotes about how you've managed some of that pricing pressure, contracting pressure, etc. in the past. It might just be useful if you can walk people through how the market has been.
>
> **Defendant Gonzalez**: Well, I think it is interesting what you point out. I think if you look at the RA market, there are probably today somewhere in the neighborhood of 11 or 12 innovative competitors that participate in that market and ***Humira has continued to gain share, significant share in that market and still enjoys the vast majority of new patients***. These are products that have some level of differentiation versus other products in the marketplace. ***So Humira has established itself and our ability to be able to execute within this market is very clear that we are able to compete effectively in what is a highly competitive market***. [Emphasis added].

326. The statements contained above were materially false and/or misleading because Defendant Gonzalez misrepresented and failed to disclose that AbbVie's strategy to "compete effectively" and maintain and increase Humira sales and market share included illegal kickbacks and unlawful sales and marketing tactics, which was known to Defendants or recklessly disregarded by them. Specifically, Defendant Gonzalez made materially false and/or misleading statements and/or failed to disclose that: (i) AbbVie's strategy to maintain and increase the sales growth of its blockbuster drug, Humira, relied in part upon systematic illegal kickbacks and unlawful sales and marketing tactics; (ii) such practices would foreseeably lead to heightened scrutiny by state governments and agencies; and (iii) as a result, Defendant Gonzalez's public statements were materially false and misleading at all relevant times.

327. On June 9, 2015, AbbVie presented at the Goldman Sachs Healthcare Conference. During the presentation, Goldman Sachs analyst Jami Rubin asked a question concerning the amount spent on Selling, General and Administrative expenses for supporting Humira's sales:

> On the last earnings call, Rick said that you're spending over $2.5 billion on Humira SG&A, which was a higher number than I think we and many other people were

anticipating doing our own bottoms up analysis. But obviously this has turned out to be a great investment given the superior performance of Humira, so nobody is complaining. But the question is how quickly you can cut that if you do see a more negative scenario playing out from biosimilars?

So the question is how do you cut the spend without sacrificing sales? If you cut that spend, won't that accelerate the decline in sales or can you cut that spend and maintain a sort of level of spend or might you even have to increase spending. So if you can kind of clarify that because I think that's something that investors would be comfortable understanding. At $2.5 billion, you're doing the right thing with that, but 2, 3 years from now, 3, 4 years from now as competitors come to the market and start to eat your market share, it may not be as wise to spend that much.

328. In response, Defendant Chase stated, in pertinent part:

Sure. Well, first of all, obviously Humira has been a spectacular story. ***And if you look at how the brand has performed since we spun off, it is several billion dollars higher in sales than it was even back in 2012. A big part of that has been the investment that we bolused into the program in 2012, 2013, a little bit in 2014.***

And that was really premised on the fact that we knew that we had the majority of new patient starts given our preferred position with payers and just the overall strength of the brand, and we realized that if you put specific programs in place to drive appropriate utilization of biologics, Humira would disproportionately benefit from that. And that's what we've done.

Now what I would tell you is, we look at all of our SG&A investments on a zero based basis. We run IRRs on every single program we have. So this isn't a case of Humira is a big product, let's slather money into the SG&A budget. ***To the contrary each of these were specific programs with the intent to drive Humira. And you've seen it play through in the market with the acceleration of script trends, most notably in the US. So we are very pleased***. [Emphasis added].

329. Thereafter, Jami Rubin asked the follow up question: "But are these variable costs or are they – how much of the $2.5 billion is variable? How much is fixed? What can you get rid of quickly if you needed to?" In response, Defendant Chase stated:

Well, there is certainly variable components. There is people, there is DTC, there is programs in place to drive adherence to expand the market if you will. Those are largely variable. I mean this is not a budget where we've allocated tremendous amounts of costs on overhead, this is primarily a variable budget. But it will remain there as long as the programs are driving a positive return. And that will always be the measuring stick that we apply to that budget.

330. The statements contained above were materially false and/or misleading because Defendant Chase misrepresented and failed to disclose that AbbVie's strategy and the "specific programs" designed to drive sales and "adherence" to Humira included illegal kickbacks and unlawful sales and marketing tactics, which was known to Defendants or recklessly disregarded by them. Specifically, Defendant Chase made materially false and/or misleading statements and/or failed to disclose that: (i) AbbVie's strategy to maintain and increase the sales growth of its blockbuster drug, Humira, relied in part upon systematic illegal kickbacks and unlawful sales and marketing tactics; (ii) such practices would foreseeably lead to heightened scrutiny by state governments and agencies; and (iii) as a result, Defendant Chase's public statements were materially false and misleading at all relevant times.

331. On July 24, 2015, AbbVie held its Second Quarter 2015 Earnings Call. During the question and answer portion of that call, BMO Capital Markets analyst Alex Arfaei asked for further details regarding the reasons behind Humira's performance. Defendant Chase responded, discussing the "investments" AbbVie made in the Humira brand, in the following exchange: Alex

> **Arfaei**: Regarding HUMIRA, you mentioned you are seeing accelerated market growth in the US -- very impressive US performance, by the way. Are you seeing increased penetration of biologics in these markets, or is it overall volume growth or both? And can you provide more color on some of the efficiencies we are seeing, some of the operating efficiencies we are seeing? Where are you cutting and why? Thank you.
>
> **Defendant Chase**: So Alex, on HUMIRA, if you look at the US, it's really been a remarkable story. If you look at market growth last year, it was in the 6% range. That has now moved to about a 13%. We've held that pretty steady across the quarter. ***So what that's a sign of is that the SG&A that we put behind the brand continues to work and it continues to give a positive return. And the way that that growth is delivered is in fact by penetration, as well as improved patient compliance and a number of other things.*** But there's definitely a penetration element. That is the big growth driver in this market and as you know, all of the immuno -- autoimmune segments are relatively underpenetrated versus what you would expect given the power of a biologic. So that is a big part of the story.
>
> In terms of efficiencies, look, we've been focused on efficiencies from the very beginning. Now they shake out in a number of different places. In manufacturing, they

> are the traditional efficiencies you would expect, whether it be purchasing, better utilization of plants or in some cases even taking offline nonproductive capacity. We've done all of those sorts of things. Across the P&L though, leverage itself presents a different type of efficiency. We are obviously no longer in a situation where we need to grow expense at the same rate as the top line. ***In fact, if you look at our expense growth, particularly on SG&A, it is far, far, far below what the top line is growing and that's pretty much the new model for this business now that we've made the investments we needed to make back in 2013 and 2014 and we are on track to start delivering growth through the introduction of new products in 2015 and beyond.*** So there's really two different types of efficiencies in the numbers. [Emphasis added].

332. The statements contained above were materially false and/or misleading because Defendant Chase misrepresented and failed to disclose that AbbVie's strategy of SG&A investment in Humira to drive sales and growth included funding a program of illegal kickbacks and unlawful sales and marketing tactics, which was known to Defendants or recklessly disregarded by them. Specifically, Defendant Chase made materially false and/or misleading statements and/or failed to disclose that: (i) AbbVie's strategy to maintain and increase the sales growth of its blockbuster drug, Humira, relied in part upon systematic illegal kickbacks and unlawful sales and marketing tactics; (ii) such practices would foreseeably lead to heightened scrutiny by state governments and agencies; and (iii) as a result, Defendant Chase's public statements were materially false and misleading at all relevant times.

333. On July 29, 2015, less than a week after Defendant Chase's misrepresentation on the Second Quarter 2015 Earnings Call, Defendant Gonzalez sold 65,000 shares of AbbVie stock for proceeds of $4,622,941.07.

334. On September 18, 2015, AbbVie presented at the Morgan Stanley Healthcare Conference. During the question and answer portion of the presentation, Morgan Stanley analyst David Risinger asked a question regarding the drivers of Humira's growth. Defendant Chase responded, stating in the following exchange:

> **David Risinger**: That's a great kick-off. Thank you. So, with respect to Humira in the US, obviously the growth has been phenomenal. Could you just talk about ongoing volume drivers ahead and additional price opportunities?

> **Defendant Chase**: . . . . So, ***what we did in 2012 and 2013, knowing that – we made very targeted SG&A investments that were drive -- that sought to drive patients to have better uptake on biologics; get on biologics sooner; as well as, once on a biologic, improve compliance so that it incrementally approached what you see in clinical environment.***
>
> And you add all of those things together, and what you see is a beautiful thing. The brand is accelerating. I think we're driving growth of the market in general. And our script trends 16%, 18%. ***And it's just -- it's a combination of what the brand has to offer, the market growth, and then some very, very intelligently invested SG&A.*** [Emphasis added].

335. Defendant Chase continued to discuss AbbVie's strategy for driving Humira growth and the investment AbbVie made in selling Humira, stating in pertinent part:

> I think initially people were somewhat surprised when they found out that the spend on Humira was approaching $2.5 billion. ***And that number is an accurate number. And the reason that number exists the way it does, is -- goes right back to the targeted investments we made in 2013 and late 2012, because we knew we were getting the majority of new patients on biologics.***
>
> Look, here's our philosophy on how we handle SG&A. We zero-base our budgets. We make sure every marketing program carries a positive ROI.
>
> And when we chose to make those investments, it was clear that they carried an incredible ROI. And I think the fact that we've accelerated the market overall, and certainly Humira growth in the US since we made those investments attests to. [Emphasis added].

336. The statements contained above were materially false and/or misleading because Defendant Chase misrepresented and failed to disclose that AbbVie's strategy and "targeted investments" to drive Humira's sales included funding a program of illegal kickbacks and unlawful sales and marketing tactics, which was known to Defendants or recklessly disregarded by them. Specifically, Defendant Chase made materially false and/or misleading statements and/or failed to disclose that: (i) AbbVie's strategy to maintain and increase the sales growth of its blockbuster drug, Humira, relied in part upon systematic illegal kickbacks and unlawful sales and marketing tactics; (ii) such practices would foreseeably lead to heightened scrutiny by state governments and agencies; and (iii) as a result, Defendant Chase's public statements were materially false and misleading at all relevant times.

337. On October 30, 2015, AbbVie held its Third Quarter 2015 Earnings Call. During the call, Defendant Gonzalez discussed Humira's growth and growth strategy, stating, in pertinent part:

> Moving on to slide 18, Humira's unique product profile and ***AbbVie's strong commercial execution has made Humira the number-one prescribed biologic, with the highest commercial prescription market share, including the highest percentage of new patient starts***. Humira holds a preferred or co-preferred position on managed care of more than 90% of US covered lives.
>
> Patients, physicians, and payers recognize the meaningful clinical and economic value of Humira as a treatment option for the broadest set of immune-mediated diseases. We've demonstrated that treatment with Humira is more cost-effective and saves payers on downstream costs associated with diseases like RA, Crohn's, and psoriasis. [Emphasis added].

338. The statement contained above was materially false and/or misleading because Defendant Gonzalez misrepresented and failed to disclose that AbbVie's commercial strategy to maintain and increase Humira sales and market share included illegal kickbacks and unlawful sales and marketing tactics, which was known to Defendants or recklessly disregarded by them. Specifically, Defendant Gonzalez made a materially false and/or misleading statement and/or failed to disclose that: (i) AbbVie's strategy to maintain and increase the sales growth of its blockbuster drug, Humira, relied in part upon systematic illegal kickbacks and unlawful sales and marketing tactics; (ii) such practices would foreseeably lead to heightened scrutiny by state governments and agencies; and (iii) as a result, Defendant Gonzalez's public statement was materially false and misleading at all relevant times.

339. On January 16, 2016, AbbVie presented at the JPMorgan Healthcare Conference. During the presentation, Defendant Gonzalez discussed the drivers of Humira's growth and the strategy for future growth of the Humira brand, stating in pertinent part:

> ***Growth of Humira over the next several years will be driven by continued biologic penetration rates increasing across disease categories and new indications***. I'll talk more about the comprehensive plan we have in place to increase and grow our leadership position in immunology in just a couple of moments.
>
> ***

> Our strong long-term guidance is built in part upon our confidence in the longevity of Humira. Our growth outlook for Humira is based on a thorough analysis of global market dynamics ***and the comprehensive four point strategy that we have put in place***.
>
> ***Humira's unique product profile and AbbVie's strong commercial execution has made Humira the number one prescribed biologic with the highest commercial prescription market share and the highest percentage of new patient starts.***
>
> Humira also holds a preferred or co-preferred position on managed care representing more than 90% of US covered lives. Patients, physicians and payers recognize the meaningful clinical and economic value of Humira as a treatment option for the broadest set of immune-mediated diseases. [Emphasis added].

340. The statements contained above were materially false and/or misleading because Defendant Gonzalez misrepresented and failed to disclose that AbbVie's commercial strategy to maintain and increase Humira sales and market share included illegal kickbacks and unlawful sales and marketing tactics, which was known to Defendants or recklessly disregarded by them. Specifically, Defendant Gonzalez made materially false and/or misleading statements and/or failed to disclose that: (i) AbbVie's strategy to maintain and increase the sales growth of its blockbuster drug, Humira, relied in part upon systematic illegal kickbacks and unlawful sales and marketing tactics; (ii) such practices would foreseeably lead to heightened scrutiny by state governments and agencies; and (iii) as a result, Defendant Gonzalez's public statements were materially false and misleading at all relevant times.

341. On February 19, 2016, Defendants caused the Company to file with the SEC an annual report for the fiscal year ended December 31, 2015 on Form 10-K (the "2015 10-K"). The 2015 10-K was signed by Defendants Gonzalez and Chase. The 2015 10-K also contained signed SOX certifications by Defendants Gonzalez and Chase attesting to the accuracy of financial reporting, the disclosure of any material changes to the Company's internal controls over financial reporting, and the disclosure of all fraud. Further, Defendants Gonzalez, Alpern, Burnside, Rapp, Tilton, Austin, Liddy, Waddell, Chase, and non-party Roberts all signed the 2015 10-K.

342. The 2015 10-K enumerated the Company's strategic objectives for 2016 to increase "HUMIRA sales growth[]":

> ***2016 Strategic Objectives***
>
> AbbVie's mission is to be an innovation-driven, patient-focused specialty biopharmaceutical company capable of achieving top-tier financial performance through outstanding execution and a consistent stream of innovative new medicines. AbbVie intends to continue to advance its mission in a number of ways, including (i) growing revenues through continued strong performance from its existing portfolio of on-market products, including its flagship brands, HUMIRA, IMBRUVICA and VIEKIRA PAK, as well as growth from pipeline products; (ii) expanding gross and operating margins; (iii) continued investment in its pipeline in support of opportunities in immunology, oncology, and virology, as well as continued investment in key on-market products; (iv) augmentation of its pipeline through concerted focus on strategic licensing, acquisition and partnering activity with a focus on identifying compelling programs that fit AbbVie's strategic criteria; and (v) returning cash to shareholders via dividends and share repurchases. In addition, AbbVie anticipates several regulatory submissions and key data readouts from key clinical trials in 2016.
>
> AbbVie expects to achieve its revenue growth objectives as follows:
>
> - HUMIRA sales growth by driving biologic penetration across disease categories, increasing market leadership, strong commercial execution and expansion to new indications for hidradenitis suppurativa (regulatory approval in the United States and EU achieved in 2015) and uveitis (regulatory submissions in the United States and the EU are under review with approval expected in 2016).

343. The 2015 10-K stated the Company is subject to anti-kickback laws and state laws relating to sales and marketing practices, stating in relevant part:

> ***Laws and regulations affecting government benefit programs could impose new obligations on AbbVie, require it to change its business practices, and restrict its operations in the future.***
>
> The health care industry is subject to various federal, state, and international laws and regulations pertaining to government benefit programs reimbursement, rebates, price reporting and regulation, and health care fraud and abuse. In the United States, these laws include anti-kickback and false claims laws, the Medicaid Rebate Statute, the Veterans Health Care Act, and individual state laws relating to pricing and sales and marketing practices. Violations of these laws may be punishable by criminal and/or civil sanctions, including, in some instances, substantial fines, imprisonment, and exclusion from participation in federal and state health care programs, including

> Medicare, Medicaid, and Veterans Administration health programs. These laws and regulations are broad in scope and they are subject to change and evolving interpretations, which could require AbbVie to incur substantial costs associated with compliance or to alter one or more of its sales or marketing practices. In addition, violations of these laws, or allegations of such violations, could disrupt AbbVie's business and result in a material adverse effect on its business and results of operations.

344. On March 17, 2016, AbbVie presented at the Barclays Global Healthcare Conference. During the presentation, Defendant Chase stated, in pertinent part:

> And then outside of the US, we are anticipating biosimilar competition in the fourth quarter of 2018. So that is how we build our models.
>
> ***The other thing we like to remind people is, even when a biosimilar competitor comes to market, we've got commercial strategies that we think can do a very, very good job of ensuring long-term durability of HUMIRA in the US that has to do with our preferred position of payers and the difficulty in switching a well-controlled patient and the familiarity that the HUMIRA brand has from a safety standpoint from a halo of indications***.
>
> So even after the biosimilar comes to market, we have commercial strategies that we think and feel very confident will in the long term blunt the impact of biosimilars. [Emphasis added].

345. The statement contained above was materially false and/or misleading because Defendant Chase misrepresented and failed to disclose the following adverse facts pertaining to AbbVie's commercial strategies to drive Humira sales, which were known to Defendants or recklessly disregarded by them. Specifically, Defendant Chase made a materially false and/or misleading statement and/or failed to disclose that: (i) AbbVie's strategy to maintain and increase the sales growth of its blockbuster drug, HUMIRA, relied in part upon systematic illegal kickbacks and unlawful sales and marketing tactics; (ii) such practices would foreseeably lead to heightened scrutiny by state governments and agencies; and (iii) as a result, Defendant Chase's public statement was materially false and misleading at all relevant times.

346. On March 21, 2016, the Company filed with the SEC a Schedule 14A (the "2016 Proxy Statement").

347. The 2016 Proxy Statement states that the Company's executive officers submit annually certifications related to their compliance with the Code of Conduct and that the Company requires mandatory training on its code of conduct. The 2016 Proxy Statement was false and misleading as the Company's Code of Conduct and Governance Guidelines were not followed as a result of the misconduct detailed herein.

348. The 2016 Proxy Statement was also false and misleading regarding the payment of executive compensation. For example, the 2016 Proxy Statement purported to employ a "pay-for performance process" known as a Performance Incentive Plan ("PIP") and at the same time failed to disclose that the Company's financial prospects were false and misleading, causing the Company's stock to be artificially inflated and allowing Defendants to wrongfully benefit. In addition, the 2016 Proxy Statement failed to disclose that: (a) the Company engaged in a kickback scheme, leading to increased scrutiny from governmental agencies; and (b) the Company failed to maintain internal controls.

349. In addition, the 2016 Proxy Statement solicited the votes of shareholders and stated as follows:

> We ask that stockholders approve the material terms of the performance goals under the AbbVie Performance Incentive Plan to satisfy the stockholder approval component of the performance-based compensation requirements under Section 162(m) of the Internal Revenue Code.
>
> The Performance Incentive Plan (PIP) provides for awards to designated AbbVie employees based on the attainment of specified performance goals. The main purposes of the PIP are to facilitate the attraction, motivation and retention of key management employees and to encourage them to achieve and exceed the company's established financial, operational and strategic goals by giving them the opportunity to earn annual incentive awards based on company and individual performance against these goals.
>
> Section 162(m) of the Internal Revenue Code limits the amount of compensation that may be deducted by the company in any tax year with respect to the company's most highly-paid executives. However, certain performance-based compensation that has been approved by stockholders is not subject to this deduction limit. The PIP is designed to provide for this type of performance-based compensation and to permit the company to claim the corresponding tax deduction.

* * *

Performance Goals

All awards payable under the PIP are based on the company's consolidated net earnings. If the company does not have consolidated net earnings, no awards are payable under the plan. The amount of a participant's award is determined as follows: the PIP plan document sets the base award allocation for the Chief Executive Officer at .0015 of the consolidated net earnings of the company for the fiscal year, the base award allocation for the Chief Operating Officer at .0010 of consolidated net earnings, and the base award allocation for any other participant at .00075 of consolidated net earnings. After the fiscal year ends and consolidated net earnings are determined, the compensation committee assesses each participant's contributions and determines the actual awards by adjusting each individual's base award allocation based on his or her performance against company financial, operational and strategic goals and individual goals during the year.

350. The solicitation was successful and the shareholders voted to approve the PIP.

351. In order to profit using the PIP, Defendants needed to show net earnings from their illegal kickback scheme and unlawful sales and marketing practices in order to generate the payments.

352. As set forth herein, Defendants caused the financial statements of the Company to be false and misleading as they used the unsustainable financial results generated by their illegal kickback scheme and unlawful sales and marketing practices to inflate the earnings and revenues of the Company. They also caused the price of the Company's stock to be artificially inflated.

353. Upon information and belief, Senior Executive Officers received payments under the PIP, during the same time they were making insider sales of Company stock.

354. The Performance Incentive Plan provided as follows:

Consolidated Net Earnings. "Consolidated Net Earnings" shall be the consolidated net earnings for such fiscal year as stated in AbbVie's Audited Financial Statements, shall reflect the incremental cost of FAS 123(R) in the current year and may, at the Compensation Committee's discretion, be adjusted to exclude acquired in-process research and development costs, and other specified items, net of income taxes.

355. As forth herein, Defendants caused the financial statements of the Company to be false and misleading because of their involvement in the illegal kickback scheme and unlawful sales

and marketing practices and boosted the Company's Consolidated Net Earnings in order to benefit from the PIP.

356. This misconduct by the Defendants continued in 2017, 2018 and thereafter. Upon information and belief, Senior Executive Officers continued to receive payments under the PIP which they otherwise were not entitled to received, had the Company's Consolidated Net Earnings not been illegally increased by the kickback scheme.

357. Accordingly, Defendants must obtain the disgorgement of all ill-gotten gains received by Senior Executive Officers.

358. On May 6, 2016, the Company filed its quarterly report for the first quarter of 2016 on Form 10-Q (the "Q1 2016 10-Q") with the SEC, which provided the Company's quarterly financial results and position. The Q1 2016 10-Q was signed by Defendants Gonzalez and Chase.

359. The Q1 2016 10-Q enumerated the drivers of Humira's sales growth in the quarter, stating, in pertinent part:

> Global HUMIRA sales for the first quarter of 2016 increased 19% ***primarily as a result of market growth across therapeutic categories and geographies and favorable pricing in certain geographies***. In the United States, HUMIRA revenues increased 32% ***driven by prescription volume, favorable pricing, and market growth across all indications***. Internationally, HUMIRA revenues increased 5%, driven primarily by growth across indications in certain geographies. AbbVie continues to pursue several new indications to help further differentiate HUMIRA from competing products and add to the sustainability and future growth of HUMIRA. [Emphasis added].

360. The statements contained above were materially false and/or misleading because Defendants misrepresented and failed to disclose that the growth of Humira sales relied, in part, on illegal kickbacks and unlawful sales and marketing tactics, which was known to Defendants or recklessly disregarded by them. Specifically, Defendants made materially false and/or misleading statements and/or failed to disclose that: (i) AbbVie's strategy to maintain and increase the sales growth of its blockbuster drug, Humira, relied in part upon systematic illegal kickbacks and unlawful sales and marketing tactics; (ii) such practices would foreseeably lead to heightened

scrutiny by state governments and agencies; and (iii) as a result, Defendants' public statement were materially false and misleading at all relevant times.

361. The statements contained above alleged to be materially false and misleading concerning the quarterly growth of Humira's sales were repeated, in all material respects, in AbbVie's Forms 10-Q filed on August 5, 2016, November 7, 2016, and May 5, 2017, and were materially false and misleading.

362. On May 23, 2016, AbbVie presented at the UBS Global Healthcare Conference. During the presentation, Defendant Chase stated, in pertinent part:

> The other nice story we have with -- on our spending profile is the fact that we've got a very rapidly-growing top line. Our top line in Q1 grew 22%.
>
> We're obviously not increasing expenses anywhere near that rate. And so, you see some nice operating margin improvement. In terms of what we do as the LOE event plays out, when it plays out, what we have told the market is, you can be absolutely certain that we're going to protect the bottom line to the greatest extent possible. There is a sizeable spend on Humira today, and we view that as very, very productive spend. If you look at TRx growth in the United States, it's been pretty clear that over the last couple of years volume has increased in the market and that is exclusively, in the case of Humira, due to the promotional programs we have in place. So, these are very, very high ROI-generating investments.

363. The statements contained above were materially false and/or misleading because Defendant Chase misrepresented and failed to disclose the following adverse facts pertaining to AbbVie's promotional programs used to drive Humira sales, which were known to Defendants or recklessly disregarded by them. Specifically, Defendant Chase made false and/or misleading statements and/or failed to disclose that: (i) AbbVie's strategy to maintain and increase the sales growth of its blockbuster drug, HUMIRA, relied in part upon systematic illegal kickbacks and unlawful sales and marketing tactics; (ii) such practices would foreseeably lead to heightened scrutiny by state governments and agencies; and (iii) as a result, Defendant Chase's public statements were materially false and misleading at all relevant times.

364. A few days after Defendant Chase's false statements on May 23, 2016, Defendant Gonzalez sold 285,953 shares of AbbVie stock on June 2, 2016 for proceeds of $18,233,001.30.

365. On October 28, 2016, AbbVie held its Third Quarter 2016 Earnings Call. During the call, Defendant Chase discussed Humira's sales and the outlook for Humira's sales for full year 2016, stating, in pertinent part:

> Humira delivered another quarter of strong sales growth with global sales of more than $4 billion, up 12.1% operationally. Globally, we continue to see strong volume growth across all therapeutic segments.
>
> In the US, Humira sales increased 16.7% compared to the prior year. The growth rate in the quarter was negatively impacted by 4 points due to higher customer ordering patterns in the prior year, a reversal of what we experienced with second quarter growth rates. Normalized for this, Humira performance in the quarter exceeded 20% comprised of low teens prescription growth and single-digit price. Wholesaler inventory levels remain below half a month across all periods.
>
> On a year-to-date basis, Humira US sales growth exceeds 24%. For the fourth quarter, we forecast sales growth in excess of 20%, which will contribute to our full-year forecast of above 20%.
>
> International Humira sales were more than $1.4 billion in the quarter, up 4.5% on an operational basis. Biosimilar Remicade has not had a material impact on performance and the Enbrel biosimilar continues to perform in line with our previously communicated assumptions. We continue to forecast Humira international operational sales growth in the mid-single digits for the full year.
>
> ***Humira's unique product profile and AbbVie's strong commercial execution has made Humira the number one prescribed biologic and we continue to see strong momentum for Humira as market leader around the world***.
>
> ***
>
> If you look at the US, the US has had just truly outstanding growth. If you look at the past six quarters, on average Humira has averaged about 25% growth. The last two quarters, second and third quarter, if you average the two of them together, the growth was 21.7%. If you make the adjustment for the ordering patterns that Bill described, third quarter was just over 20% growth.
>
> ***And as Bill indicated, we are forecasting 20% growth again in the fourth quarter. The October weeklies are consistent with that; we obviously pay a lot of attention to Humira. This brand continues to grow extremely well and the vast majority of that growth is volume.***

> If you look at market share, in the US we continue to perform well. Probably the best way look at market share would be if you track it at the beginning of 2016 and look at it through the latest data points that we have, which would be September data points, the overall market share for Humira is about 31.8%. It's up 0.6% over that period of time from January through September.
>
> Rheumatology, our share is 26.8%. It has increased a full point over that period of time. Gastro and derm, our market share remains basically flat at 43% and 35% market share. ***This brand continues to perform extremely well in the marketplace and it's because of the attributes of this product and how well-accepted is it by physicians and by patients***.
>
> We are continuing to see good market growth. There is an anomaly in the IMS data because a large managed care organization has blinded their data, but it's still in the base. But what I would tell you is that if you look at script growth on Humira, it's above 13% when you make the appropriate adjustments and the market is growing high single digits, around 9% or so. So prescription growth continues to be extremely robust.
>
> ***
>
> In terms of Humira, we are not backing off our spend on Humira. ***The spend on Humira has been the driver of the spectacular growth that the brand has put up and all of those programs are very, very high ROI, which as you can see -- as you can imagine, based on the sales growth.*** [Emphasis added].

366. The statements contained above were materially false and/or misleading because Defendant Chase misrepresented and failed to disclose that the "programs" AbbVie utilized to drive Humira's sales growth included illegal kickbacks and unlawful sales and marketing tactics, which was known to Defendants or recklessly disregarded by them. Specifically, Defendant Chase made materially false and/or misleading statements and/or failed to disclose that: (i) AbbVie's strategy to maintain and increase the sales growth of its blockbuster drug, Humira, relied in part upon systematic illegal kickbacks and unlawful sales and marketing tactics; (ii) such practices would foreseeably lead to heightened scrutiny by state governments and agencies; and (iii) as a result, Defendant Chase's public statements were materially false and misleading at all relevant times.

367. On January 27, 2017, AbbVie held its Fourth Quarter 2016 Earnings Call. During the call, Defendant Chase discussed Humira's sales and the outlook for Humira's sales for the quarter and full year 2017, stating, in pertinent part:

> Humira delivered another quarter of strong growth with global sales of $4.3 billion, up 16.2% operationally. In the US, Humira sales increased 23.5% compared to the prior year, driven by volume growth of roughly 14% plus price. Wholesaler inventories remained below half a month in the quarter.
>
> ***
>
> For the full year 2016, global Humira sales were $16.1 billion, reflecting incremental sales of more than $2 billion. Full-year sales of Humira in the US grew more than 24% with midteens prescription growth and a contribution from price in the high single-digits.
>
> ***
>
> ***This exceptional performance was driven by Humira's overall level of efficacy and safety, long physician experience, and continued biologic penetration across disease categories. Its unique product profile and AbbVie's strong commercial execution has made Humira the number one prescribed biologic and it remains the undisputed market leader, despite competition***. [Emphasis added].

368. The statements contained above were materially false and/or misleading because Defendant Chase misrepresented and failed to disclose that Humira's "performance" was driven, in part, by illegal kickbacks and unlawful sales and marketing tactics, which was known to Defendants or recklessly disregarded by them. Specifically, Defendant Chase made materially false and/or misleading statements and/or failed to disclose that: (i) AbbVie's strategy to maintain and increase the sales growth of its blockbuster drug, Humira, relied in part upon systematic illegal kickbacks and unlawful sales and marketing tactics; (ii) such practices would foreseeably lead to heightened scrutiny by state governments and agencies; and (iii) as a result, Defendant Chase's public statements were materially false and misleading at all relevant times.

369. On February 17, 2017, Defendants caused the Company to file with the SEC an annual report for the fiscal year ended December 31, 2016 on Form 10-K (the "2016 10-K"). The 2016 10-K was signed by Defendants Gonzalez and Chase. The 2016 10-K also contained signed SOX certifications by Defendants Gonzalez and Chase attesting to the accuracy of financial reporting, the disclosure of any material changes to the Company's internal controls over financial

reporting, and the disclosure of all fraud. Further, Defendants Gonzalez, Alpern, Burnside, Liddy, Tilton, Austin, Hart, Rapp, Waddell and Chase all signed the 2016 10-K.

370. The 2016 10-K enumerated the Company's strategic objectives for 2017 to drive "HUMIRA sales growth[]":

> ***2017 Strategic Objectives***
>
> AbbVie's mission is to be an innovation-driven, patient-focused specialty biopharmaceutical company capable of achieving top-tier financial performance through outstanding execution and a consistent stream of innovative new medicines. AbbVie intends to continue to advance its mission in a number of ways, including: (i) growing revenues through continued strong performance from its existing portfolio of on-market products, including its flagship brands, HUMIRA and IMBRUVICA as well as growth from pipeline products; (ii) expanding operating margins; (iii) continued investment in its pipeline in support of opportunities in immunology, oncology, virology and neurology as well as continued investment in key on-market products; (iv) augmentation of its pipeline through concerted focus on strategic licensing, acquisition and partnering activity with a focus on identifying compelling programs that fit AbbVie's strategic criteria; and (v) returning cash to shareholders via dividends and share repurchases. In addition, AbbVie anticipates several regulatory submissions and key data readouts from key clinical trials in the next twelve months.
>
> AbbVie expects to achieve its strategic objectives as follows:
>
> - HUMIRA sales growth by driving biologic penetration across disease categories, increasing market leadership, strong commercial execution.

371. The 2016 10-K stated the Company is subject to anti-kickback laws and state laws relating to sales and marketing practices, stating in relevant part:

> ***Laws and regulations affecting government benefit programs could impose new obligations on AbbVie, require it to change its business practices, and restrict its operations in the future.***
>
> The health care industry is subject to various federal, state and international laws and regulations pertaining to government benefit programs reimbursement, rebates, price reporting and regulation and health care fraud and abuse. In the United States, these laws include anti-kickback and false claims laws, the Medicaid Rebate Statute, the Veterans Health Care Act and individual state laws relating to pricing and sales and marketing practices. Violations of these laws may be punishable by criminal and/or civil sanctions, including, in some instances, substantial fines, imprisonment and

> exclusion from participation in federal and state health care programs, including Medicare, Medicaid and Veterans Administration health programs. These laws and regulations are broad in scope and they are subject to change and evolving interpretations, which could require AbbVie to incur substantial costs associated with compliance or to alter one or more of its sales or marketing practices. In addition, violations of these laws, or allegations of such violations, could disrupt AbbVie's business and result in a material adverse effect on its business and results of operations. [Emphasis added].

372. On March 20, 2017, Defendants caused the Company to file with the SEC a Schedule 14A (the "2017 Proxy Statement").

373. The 2017 Proxy Statement states that the Company's executive officers submit annually certifications related to their compliance with the Code of Conduct and that the Company requires mandatory training on its code of conduct. The 2017 Proxy Statement was false and misleading as the Company's Code of Conduct and Governance Guidelines were not followed as a result of the misconduct detailed herein.

374. Defendants caused the 2017 Proxy Statement to be false and misleading regarding the executive compensation. For example, the 2017 Proxy Statement purported to employ a "pay-for performance process" and at the same time failing to disclose that the Company's financial prospects were false and misleading, causing the Company's stock to be artificially inflated and allowing Defendants to wrongfully benefit. In addition, the 2017 Proxy Statement failed to disclose that: (a) the Company engaged in a kickback scheme, leading to increased scrutiny from governmental agencies; and (b) the Company failed to maintain internal controls.

375. On April 27, 2017 during the Company's Q1 2017 Earnings Call with investors, Defendant Gonzalez stated: "In the U.S. Humira grew 22.8%, driven by robust underlying demand, including prescription volume growth of 12%."

376. The statement contained above was materially false and/or misleading because Defendant Gonzalez misrepresented and failed to disclose the following adverse facts pertaining to the growth of Humira's sales, which were known to Defendants or recklessly disregarded by them. Specifically, Defendant Gonzalez made a materially false and/or misleading statement and/or failed

to disclose that: (i) AbbVie's strategy to maintain and increase the sales growth of its blockbuster drug, Humira, relied in part upon systematic illegal kickbacks and unlawful sales and marketing tactics; (ii) such practices would foreseeably lead to heightened scrutiny by state governments and agencies; and (iii) as a result, Defendant Gonzalez's public statement was materially false and misleading at all relevant times.

377. Defendant Gonzalez capitalized on his false statements, selling 71,235 shares of his AbbVie stock for $4,665,386.91 on May 19, 2017.

378. On May 22, 2017, AbbVie presented at the UBS Global Healthcare Conference. During the presentation, in response to a question from UBS analyst Marc Harold Goodman, Defendant Gonzalez stated:

> This has been a category where there has been and continues to be a tremendous amount of competition. But yet we have continued to grow. In fact, what you've seen is that HUMIRA's growth has actually accelerated. If you go back to 2011, 2012 and you look at the growth rates, the growth rates have accelerated pretty dramatically starting in 2013. Much of that is driven by the efforts that we had put in place to expand biological penetration. And what we mean by that is getting patients on a therapy that ultimately will put their disease under control or in remission as rapidly as possible. That's a theme that we drive in the marketplace because what we found through market research is that patients prior to that would stay on ineffective DMARD therapy sometimes for 7 to 10 years, as an example, and not move to a biologic. So our whole philosophy is drive the patient through a therapy that ultimately will be able to give them the kind of effect that you want and we will get more than our fair share. And clearly, that has played out the way we've expected it to.

379. The statements contained above were materially false and/or misleading because Defendant Gonzalez misrepresented and failed to disclose the following adverse facts pertaining to AbbVie's "efforts" to expand Humira's patient penetration and drive Humira sales, which were known to Defendants or recklessly disregarded by them. Specifically, Defendant Gonzalez made false and/or misleading statements and/or failed to disclose that: (i) AbbVie's strategy to maintain and increase the sales growth of its blockbuster drug, Humira, relied in part upon systematic illegal kickbacks and unlawful sales and marketing tactics; (ii) such practices would foreseeably lead to

heightened scrutiny by state governments and agencies; and (iii) as a result, Defendant Gonzalez's public statements were materially false and misleading at all relevant times.

380. On August 7, 2017, the Company filed its quarterly report for the second quarter of 2017 on Form 10-Q (the "Q2 2017 10-Q") with the SEC, which provided the Company's quarterly financial results and position. The Q2 2017 10-Q was signed by Defendants Gonzalez and Chase.

381. The Q2 2017 10-Q enumerated the drivers of Humira's sales growth in the quarter, stating in pertinent part:

> Global HUMIRA sales increased 15% for both the three and six months ended June 30, 2017 ***primarily as a result of market growth across therapeutic categories and geographies as well as favorable pricing in certain geographies***. In the United States, HUMIRA sales increased 18% for the three months and 20% for the six months ended June 30, 2017 ***driven by market growth across all indications and favorable pricing***. Internationally, HUMIRA sales increased 9% for the three months and 7% for the six months ended June 30, 2017 driven primarily by market growth and tender timing. AbbVie continues to pursue strategies intended to further differentiate HUMIRA from competing products and add to the sustainability and future growth of HUMIRA. [Emphasis added].

382. The statements contained above were materially false and/or misleading because Defendants misrepresented and failed to disclose that the growth of Humira sales relied, in part, on illegal kickbacks and unlawful sales and marketing tactics, which was known to Defendants or recklessly disregarded by them. Specifically, Defendants made materially false and/or misleading statements and/or failed to disclose that: (i) AbbVie's strategy to maintain and increase the sales growth of its blockbuster drug, Humira, relied in part upon systematic illegal kickbacks and unlawful sales and marketing tactics; (ii) such practices would foreseeably lead to heightened scrutiny by state governments and agencies; and (iii) as a result, Defendants' public statements were materially false and misleading at all relevant times.

383. That same day, Defendant Gonzalez sold 193,131 shares of his AbbVie stock for proceeds of $13,713,242.59.

384. The statements contained above alleged to be materially false and misleading concerning the quarterly growth of Humira's sales were repeated, in all material respects, in

AbbVie's Forms 10-Q filed on November 7, 2017 and May 4, 2018 and were materially false and misleading when made.

385. On January 26, 2018, AbbVie held its Fourth Quarter 2017 Earnings Call. During the call, Defendant Chase discussed the reasons reflecting Humira's success, stating, in pertinent part:

> Fourth quarter global sales of HUMIRA were $4.9 billion, up 12.3% operationally, driven by strong demand. HUMIRA sales in the U.S. were up 15.1% year-overyear, reflecting volume of approximately 10% plus price. International HUMIRA sales were $1.6 billion in the quarter, an increase of 6.5% operationally or 11.7% on a reported basis. Sales growth in the quarter benefited from the timing of tenders in select markets, which contributed approximately 2.5% to the growth rate. Global HUMIRA sales for the full year 2017 were $18.4 billion, reflecting operational sales growth of 14.4%. HUMIRA remains the undisputed market leader across the broadest range of therapeutic indications, reflecting its strong position with physicians, unique product profile and strong commercial execution.

386. The statement contained above was materially false and/or misleading because Defendant Chase misrepresented and failed to disclose that the "strong commercial execution" and Humira's position as a "market leader" was driven, in part, by illegal kickbacks and unlawful sales and marketing tactics, which was known to Defendants or recklessly disregarded by them. Specifically, Defendant Chase made a materially false and/or misleading statement and/or failed to disclose that: (i) AbbVie's strategy to maintain and increase the sales growth of its blockbuster drug, Humira, relied in part upon systematic illegal kickbacks and unlawful sales and marketing tactics; (ii) such practices would foreseeably lead to heightened scrutiny by state governments and agencies; and (iii) as a result, Defendant Chase's public statement was materially false and misleading at all relevant times.

387. That same day, AbbVie's stock price increased to $125.86.

388. On February 16, 2018, Defendants caused the Company to file with the SEC its annual report for the fiscal year ended December 31, 2017 on Form 10-K (the "2017 10-K"). The 2017 10-K was signed by Defendants Gonzalez and Chase. The 2017 10-K also contained signed SOX certifications by Defendants Gonzalez and Chase attesting to the accuracy of financial

reporting, the disclosure of any material changes to the Company's internal controls over financial reporting, and the disclosure of all fraud. Further, Defendants Gonzalez, Alpern, Burnside, Liddy, Tilton, Austin, Hart, Rapp, Meyer, Waddell and Chase all signed the 2017 10-K.

389. The 2017 10-K enumerated the Company's strategic objectives for 2018 to drive "HUMIRA sales growth[,]":

> ***2018 Strategic Objectives***
>
> AbbVie's mission is to be an innovation-driven, patient-focused specialty biopharmaceutical company capable of achieving top-tier financial performance through outstanding execution and a consistent stream of innovative new medicines. AbbVie intends to continue to advance its mission in a number of ways, including: (i) growing revenues by diversifying revenue streams, driving late-stage pipeline assets to the market and ensuring strong commercial execution of new product launches; (ii) continued investment and expansion in its pipeline in support of opportunities in immunology, oncology and neurology as well as continued investment in key on-market products; (iii) expanding operating margins; and (iv) returning cash to shareholders via dividends and share repurchases. In addition, AbbVie anticipates several regulatory submissions and key data readouts from key clinical trials in the next twelve months.
>
> AbbVie expects to achieve its strategic objectives through:
>
> - HUMIRA sales growth by driving biologic penetration across disease categories, increasing market leadership, strong commercial execution and expansion.

390. The 2017 10-K stated the Company is subject to anti-kickback laws and state laws relating to sales and marketing practices, stating in relevant part:

> ***Laws and regulations affecting government benefit programs could impose new" obligations on AbbVie, require it to change its business practices, and restrict its operations in the future.***
>
> The health care industry is subject to various federal, state and international laws and regulations pertaining to government benefit programs reimbursement, rebates, price reporting and regulation and health care fraud and abuse. In the United States, these laws include anti-kickback and false claims laws, the Medicaid Rebate Statute, the Veterans Health Care Act and individual state laws relating to pricing and sales and marketing practices. Violations of these laws may be punishable by criminal and/or civil sanctions, including, in some instances, substantial fines, imprisonment and

> exclusion from participation in federal and state health care programs, including Medicare, Medicaid and Veterans Administration health programs. These laws and regulations are broad in scope and they are subject to change and evolving interpretations, which could require AbbVie to incur substantial costs associated with compliance or to alter one or more of its sales or marketing practices. In addition, violations of these laws, or allegations of such violations, could disrupt AbbVie's business and result in a material adverse effect on its business and results of operations.

391. The statements contained above were materially false and/or misleading because they misrepresented and failed to disclose the following adverse facts pertaining to the Company's business, operational and financial results, which were known to Defendants or recklessly disregarded by them. Defendants made false and/or misleading statements and/or failed to disclose that: (i) AbbVie's strategy to increase the sales growth of its blockbuster drug, HUMIRA, relied in part upon illegal kickbacks and unlawful sales and marketing tactics; (ii) such practices would foreseeably lead to heightened scrutiny by State governments and agencies; and (iii) as a result, Defendants' public statements were materially false and misleading at all relevant times.

392. On March 19, 2018, Defendants caused the Company to file with the SEC a Schedule 14A (the "2018 Proxy Statement").

393. The 2018 Proxy Statement states that the Company's executive officers submit annually certifications related to their compliance with the Code of Conduct and that the Company requires mandatory training on its code of conduct. The 2018 Proxy Statement was false and misleading as the Company's Code of Conduct and Governance Guidelines were not followed as a result of the misconduct detailed herein.

394. Defendants caused the 2018 Proxy Statement to be false and misleading regarding the executive compensation. For example, the 2018 Proxy Statement purported to employ a "pay-for performance process" and at the same time failing to disclose that the Company's financial prospects were false and misleading, causing the Company's stock to be artificially inflated and allowing Defendants to wrongfully benefit. In addition, the 2018 Proxy Statement failed to disclose

that: (a) the Company engaged in a kickback scheme, leading to increased scrutiny from governmental agencies; and (b) the Company failed to maintain internal controls.

395. On July 27, 2018, AbbVie held its Second Quarter 2018 Earnings Call. During the call, Defendant Gonzalez discussed the reasons for Humira's success, starting in pertinent part:

> Certainly, getting access in the U.S. is an important issue for any product in any category, and [rebates] play a role in that. But if you look at HUMIRA, I think there's 4, 5 important points the investors need to keep in mind. One is if you look at our percent rebate as it relates to the competitors' rebates, I would tell you that we're certainly nowhere near the highest. And in fact, we're probably in the middle or slightly below the middle from a percent rebate standpoint. The second thing I'd say is if you look at the cost of therapy for HUMIRA for those assets that are on contract, again, we're not the highest-priced product on contract, and we're not the lowest-priced product on contract. We're pretty much in the middle of the pack. ***The third thing, I think this is a very important issue. Over the course of the last couple of years, most covered lives in the United States have moved to these open formularies, and those formularies typically have between 5 and 7 products on contract with HUMIRA. And HUMIRA does extremely well in an environment where there's full choice. Physicians have total choice to prescribe any one of those drugs, and HUMIRA has maintained its position as the #1 product for capturing naive patients. And so it's not like we have this position where we have exclusive contracts where physicians have to prescribe HUMIRA. They prescribe HUMIRA because of the attributes of the product, the experience they've had, the comfort they have with the safety profile of it and the rest of the attributes of the product.***

396. The statements contained above were materially false and/or misleading because they misrepresented and failed to disclose the following adverse facts pertaining to Humira's success and the Company's marketing practices and sales strategy, which were known to Defendants or recklessly disregarded by them. Specifically, Defendant Gonzalez made materially false and/or misleading statements and/or failed to disclose that: (i) AbbVie's strategy to maintain and increase the sales growth of its blockbuster drug, Humira, relied in part upon illegal kickbacks and unlawful sales and marketing tactics; (ii) such practices would foreseeably lead to heightened scrutiny by state governments and agencies; and (iii) as a result, Defendant Gonzalez's public statements were materially false and misleading at all relevant times.

THE COMPANY'S SEC FILINGS DID NOT COMPLY WITH SEC DISCLOSURE REGULATIONS

397. Item 7 of Form 10-K and Item 2 of Form 10-Q require SEC registrants to furnish the information called for under Item 303 of Regulation S-K [17 C.F.R. § 229.303], Management's Discussion and Analysis of Financial Condition and Results of Operations (MD&A). Among other things, Item 303 of Regulation S-K required that AbbVie's Relevant Period Forms 10-K and 10- Q disclose known trends or uncertainties that had, or were reasonably likely to have, a material impact on the Company's revenues or income from continuing operations.

398. In 1989, the SEC issued interpretative guidance associated with the requirements of Item 303 of Regulation S-K concerning the disclosure of material trends or uncertainties. The interpretative guidance states in pertinent part:

> A disclosure duty exists where a trend, demand, commitment, event or uncertainty is both presently known to management and reasonably likely to have material effects on the registrant's financial condition or results of operation.
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> Events that have already occurred or are anticipated often give rise to known uncertainties. . . . In situations such as these, a registrant would have identified a known uncertainty reasonably likely to have material future effects on its financial condition or results of operations, and disclosure would be required.

399. In 2003, the SEC issued additional interpretative guidance relating to the requirements of Item 303. Such guidance states, in pertinent part:

> We believe that management's most important responsibilities include communicating with investors in a clear and straightforward manner. MD&A is a critical component of that communication. The Commission has long sought through its rules, enforcement actions and interpretive processes to elicit MD&A that not only meets technical disclosure requirements but generally is informative and transparent.
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> Financial measures generally are the starting point in ascertaining these key variables and other factors. However, financial measures often tell only part of how a company manages its business. Therefore, when preparing MD&A, companies should consider whether disclosure of all key variables and other factors that management uses to manage the business would be material to investors, and therefore required.

***

> Companies should also consider disclosing information that may be peripheral to the accounting function, but is integral to the business or operating activity. Examples of such measures, depending on the circumstances of a particular company, can include those based on units or volume, customer satisfaction, time to-market, interest rates, product development, service offerings, throughput capacity, affiliations/joint undertakings, market demand, customer/vendor relations, employee retention, business strategy, changes in the managerial approach or structure, regulatory actions or regulatory environment, and any other pertinent macroeconomic measures.

400. Thus, the MD&A disclosures in AbbVie's Forms 10-K and 10-Q filed with the SEC during the Relevant Period were materially false and misleading because Defendants failed to disclose material uncertainties and trends associated with AbbVie's improper sales and marketing practices then known to management that were reasonably likely to result in lawsuits and regulatory actions that would have a material effect on the Company's future operating results, including by ending the improper, but effective and profitable, sales and marketing practices that had increased sales of Humira for years.

401. In addition, Item 1A of both Form 10-K and Form 10-Q requires SEC registrants to furnish the information called for under Item 503 of Regulation S-K [17 C.F.R. § 229.503], Risk Factors. Item 503 of Regulation S-K required that AbbVie's Relevant Period Forms 10-K and 10-Q disclose the most significant matters that make an investment in AbbVie risky. During the Relevant Period, however, AbbVie's Forms 10-K and 10-Q instead made materially false and misleading representations about ***potential*** regulatory and legal risks when, in fact, such risks were ***then existing***.

402. The risk factor disclosure included in the Company's Forms 10-K deceptively referred ***to potential and "new" risks*** associated with anti-kickback laws and state laws relating to sales and marketing practices, when, in fact, such risks were ***then existing*** due to AbbVie's illegal kickback scheme and unlawful sales and marketing practices. These disclosures stated in pertinent part:

> Laws and regulations affecting government benefit programs ***could impose new obligations on AbbVie***, require it to change its business practices, and restrict its operations in the future.

> The health care industry is subject to various federal, state, and international laws and regulations pertaining to government benefit programs reimbursement, rebates, price reporting and regulation, and health care fraud and abuse. In the United States, these laws include anti-kickback and false claims laws, the Medicaid Rebate Statute, the Veterans Health Care Act, and individual state laws relating to pricing and sales and marketing practices. Violations of these laws may be punishable by criminal and/or civil sanctions, including, in some instances, substantial fines, imprisonment, and exclusion from participation in federal and state health care programs, including Medicare, Medicaid, and Veterans Administration health programs. These laws and regulations are broad in scope and they are subject to change and evolving interpretations, which could require AbbVie to incur substantial costs associated with compliance or to alter one or more of its sales or marketing practices. In addition, violations of these laws, or allegations of such violations, could disrupt AbbVie's business and result in a material adverse effect on its business and results of operations.

403. AbbVie's Forms 10-Q during the Relevant Period incorporated by reference this materially false and misleading risk factor disclosure.

404. Further, Item 9A of Form 10-K and Item 4 of Form 10-Q require SEC registrants to furnish the information called for under Item 307 of Regulation S-K [17 C.F.R. § 229.307], Disclosure Controls and Procedures. Item 307 of Regulation S-K required AbbVie's Relevant Period Forms 10-K and 10-Q to disclose Defendant Gonzalez's and Defendant Chase's conclusions about the effectiveness of AbbVie's disclosure controls, defined by relevant regulation as the controls and procedures designed to ensure that information required to be disclosed in reports filed with the SEC is appropriately recorded, processed, summarized, and reported.

405. During the Relevant Period, AbbVie falsely and misleadingly represented in the Forms 10-K and 10-Q it filed with SEC that its disclosure controls were operating effectively when they were not, as detailed herein. These materially false and misleading representations were then fraudulently certified by Defendants Gonzalez and Chase, as set forth herein.

406. Specifically, AbbVie's Forms 10-K and 10-Q contained materially false and misleading representations regarding AbbVie's disclosure controls being effective, when in reality

they were poorly designed and "ineffective" in assessing the risk of material misstatements. These filings stated, in pertinent part:

> **Evaluation of disclosure controls and procedures.**
>
> The Chief Executive Officer, Richard A. Gonzalez, and the Chief Financial Officer, William J. Chase, ***evaluated the effectiveness of AbbVie's disclosure controls and procedures as of the end of the period covered by this report, and concluded that AbbVie's disclosure controls and procedures were effective*** to ensure that information AbbVie is required to disclose in the reports that it files or submits with the Securities and Exchange Commission under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported, within the time periods specified in the Commission's rules and forms, and to ensure that information required to be disclosed by AbbVie in the reports that it files or submits under the Exchange Act is accumulated and communicated to AbbVie's management, including its principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. [Emphasis added].

407. The representations in the Company's Forms 10-K and 10-Q about AbbVie's disclosure controls being effective were then falsely and misleadingly certified by Defendants Gonzalez and Chase:

> I, [Defendant Gonzalez/Chase], certify that:
>
> 1. I have reviewed this annual report on Form [10-K or 10-Q] of AbbVie Inc.;
>
> 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
>
> 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of AbbVie as of, and for, the periods presented in this report;
>
> 4. AbbVie's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for AbbVie and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to AbbVie, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of AbbVie's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in AbbVie's internal control over financial reporting that occurred during AbbVie's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, AbbVie's internal control over financial reporting; and

5. AbbVie's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to AbbVie's auditors and the audit committee of AbbVie's board of directors:

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect AbbVie's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in AbbVie's internal control over financial reporting.

408. The material misstatements and omissions included in the Forms 10-K and 10-Q failed to disclose material facts required by SEC rules and regulations associated with AbbVie's reliance upon systematic illegal kickbacks and unlawful sales and marketing tactics to maintain and increase the sales growth of its blockbuster drug, Humira.

THE TRUTH BEGINS TO EMERGE

409. On September 18, 2018, *Bloomberg* published an article entitled, "California Sues AbbVie Over Alleged Arthritis Drug Kickbacks," reporting that the State of California filed a lawsuit against AbbVie for engaging in a kickback scheme aimed to boost HUMIRA sales (the "California Complaint"). The article provides that the lawsuit seeks damages involving "private insurance claims." The article states in relevant part:

> California's insurance regulator is suing AbbVie Inc., alleging that the pharmaceutical giant gave illegal kickbacks to health-care providers in order to keep patients on its blockbuster rheumatoid arthritis drug Humira.
>
> The company "engaged in a far-reaching scheme including both classic kickbacks -- cash, meals, drinks, gifts, trips, and patient referrals -- and more sophisticated ones -- free and valuable professional goods and services to physicians to induce and reward Humira prescriptions," the California Department of Insurance said in a statement.
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> According to the state, AbbVie paid for registered nurses that it called ambassadors to help doctors with patients who were taking Humira. While the nurses were represented to patients as an extension of the doctor's office, they were trained to tout the drug while downplaying its risks, the state said. "AbbVie spent millions convincing patients and health care professionals that AbbVie Ambassadors were patient advocates -- in fact, the Ambassadors were Humira advocates hired to do one thing, keep patients on a dangerous drug at any cost," Insurance Commissioner Dave Jones said in the statement.
>
> The alleged misconduct "is particularly egregious because it's well known the drug has very adverse side effects," said Jones in a press conference. Under the ambassador system, complaints or concerns about serious infections, blood problems, or even heart failure -- all known side effects of Humira -- could go unreported to patients' physicians, he said.
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> ***
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> Humira is one of the world's biggest-selling medications. The drug brought in $18.4 billion in 2017, accounting for roughly two-thirds of North Chicago, Illinois-based AbbVie's revenue. Private insurers have paid out $1.2 billion in Humira-related claims, according to Jones.
>
> ***

> Jones is intervening in a whistleblower complaint filed in California by a nurse who was employed as an AbbVie ambassador in Florida several years ago. The suit, filed in Alameda County Superior Court, seeks three times the amount of each claim made for Humira as a result of the alleged kickbacks. The lawsuit involves private insurance claims, said Nancy Kincaid, a spokeswoman for the California Department of Insurance.

410. According to the California Complaint, relator-plaintiff Lazaro Suarez worked for AbbVie via its sub-contractor, Quintiles Transactional Holdings, Inc., as a "Nurse Educator" and "Patient Ambassador" from approximately March 23, 2013 and October 2014. In that position, he "became aware of AbbVie's [kickback] scheme nationwide, including in California, because of his role as a trainer, among other ways. After leaving his employment, Mr. Suarez continued to obtain information about the allegations [described in the California Complaint], including through ongoing contacts with AbbVie and Quintiles personnel." The California Complaint states the alleged fraudulent conduct occurred from 2013 to the present.

411. On this news, shares of AbbVie fell $4.35 per share or over 4.5% over the next two consecutive trading days to close at $91.02 per share on September 19, 2018.

FALSE AND MISLEADING STATEMENTS REGARDING THE TENDER OFFER

412. On May 30, 2018, Defendants caused the Company to issue a press release announcing the preliminary results of the Tender Offer. The press release announced:

> Based on the preliminary count by Computershare Trust Company, N.A., the depositary for the tender offer, a total of 75,743,313 shares of AbbVie's common stock, $0.01 par value per share, were properly tendered and not properly withdrawn at or below the purchase price of $105 per share, including 49,129,844 shares that were tendered by notice of guaranteed delivery. AbbVie has been informed by the depositary that the preliminary proration factor for the tender offer is approximately 94.3 percent.
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> In accordance with the terms and conditions of the tender offer, and based on the preliminary count by the depositary, AbbVie expects to acquire approximately 71.4 million shares of its common stock at a price of $105 per share, for an aggregate cost of approximately $7.5 billion, excluding fees and expenses relating to the tender offer. These shares represent approximately 4.5 percent of the shares outstanding. The

> number of shares to be purchased and the purchase price are preliminary and subject to change. The preliminary information contained in this press release is subject to confirmation by the depositary and is based on the assumption that all shares tendered through notice of guaranteed delivery will be delivered within the two trading day settlement period. The final number of shares to be purchased and the final purchase price will be announced following the expiration of the guaranteed delivery period and completion by the depositary of the confirmation process. Payment for the shares accepted for purchase under the tender offer and return of all other shares tendered and not purchased, will occur promptly thereafter.

413. On this news, the price per share of Company stock was trading as high as $103.16 on May 30, 2018, ultimately closing at $103.01 on that date, which was $3.54 higher than its closing price on May 29, 2018.

THE TRUTH EMERGES

414. Later that day, on May 30, 2018, the Company issued a press release announcing updated preliminary results of the Tender Offer. The press release stated:

> This update replaces the preliminary results announced at 8:00 am, New York City time, on May 30, 2018. This update reflects additional shares that were validly tendered by notice of guaranteed delivery, but that were erroneously omitted from the initial preliminary results provided to AbbVie by Computershare Trust Company, N.A., the depositary for the tender offer. Final results of the tender offer will be issued no later than June 4, 2018 following the expiration of the notice of guaranteed delivery period.
>
> Based on the updated preliminary count by Computershare Trust Company, N.A., the depositary for the tender offer, a total of 74,033,457 shares of AbbVie's common stock, $0.01 par value per share, were properly tendered and not properly withdrawn at or below the purchase price of $103 per share, including 52,915,569 shares that were tendered by notice of guaranteed delivery. AbbVie has been informed by the depositary that the preliminary proration factor for the tender offer is approximately 98.4 percent.
>
> In accordance with the terms and conditions of the tender offer, and based on the preliminary count by the depositary, AbbVie expects to acquire approximately 72.8 million shares of its common stock at a price of $103 per share, for an aggregate cost of approximately $7.5 billion, excluding fees and expenses relating to the tender offer. These shares represent approximately 4.6 percent of the shares outstanding. The number of shares to be purchased and the purchase price are preliminary and subject to change. The preliminary information contained in this press release is subject to confirmation by the depositary and is based on the assumption that all shares tendered

> through notice of guaranteed delivery will be delivered within the two trading day settlement period. The final number of shares to be purchased and the final purchase price will be announced following the expiration of the guaranteed delivery period and completion by the depositary of the confirmation process. Payment for the shares accepted for purchase under the tender offer and return of all other shares tendered and not purchased, will occur promptly thereafter.

415. On this news, the price per share of the Company stock fell $4.07, or almost 4%, from the previous day's closing price, closing at $98.94 on May 31, 2018.

THE SALE OF HUMIRA IS A CORE OPERATION OF ABBVIE

416. Defendants' knowledge of the illicit practices discussed herein can readily be inferred because sales of Humira were absolutely critical to AbbVie's overall operations.

417. Humira is the Company's blockbuster drug, accounting for two-thirds of AbbVie's overall sales. In 2017, for example, the Company sold $18.4 billion worth of the drug worldwide, accounting for 65% of AbbVie's revenue. In 2018, global sales of Humira reached $19.9 billion, an 8.2% increase from the prior year. Since 2010, AbbVie has collected more than $115 billion in global Humira sales, 58% of which has come from U.S. sales. Indeed, Humira is the most prescribed medication in the world and its sales grew exponentially during the Relevant Period.

418. That Humira sales (and the practices that led to increased sales of the drug over the course of the Relevant Period) constitute a "core operation" at AbbVie is readily apparent from the Defendants' own statements. As detailed herein, Defendants spoke regularly about Humira's significance to the Company, the purported reasons for the growth of Humira, and the Company's strategies for driving that growth. As just one example, at a Jeffries Global Health Care presentation on November 19, 2015, Defendant Chase, recognizing the drug's importance to the Company, stated: "So HUMIRA has been a phenomenal growth driver for the company. I mean, if you look at how it's performed over the last few years, it's grown at over $1 billion per year this year. And of lately,

this quarter, almost 20% growth on the brand. So HUMIRA is obviously incredibly important and a huge cash flow generator for the company."

419. In the prior month (late October 2015), Defendant Gonzalez specifically addressed Humira's growth and growth strategy, stating that "Humira's unique product profile and AbbVie's strong commercial execution has made Humira the number-one prescribed biologic, with the highest commercial prescription market share, including the highest percentage of new patient starts."

ABBVIE OPERATES IN A HIGHLY REGULATED INDUSTRY

420. As noted in various Company SEC filings during the Relevant Period, AbbVie's marketing, sales, and promotional activities "are subject to comprehensive government regulation." Those same filings state that "[c]ompliance with these [applicable] laws and regulations is costly and materially affects AbbVie's business. . . . AbbVie expects compliance with these regulations to continue to require significant technical expertise and capital investment to ensure compliance." The Company also has indicated that a "[f]ailure to comply" in this regard "can . . . result in regulatory and enforcement actions, the seizure or recall of a product, the suspension or revocation of the authority necessary for a product's production and sale and other civil or criminal sanctions, including fines and penalties."

421. Given the existence of that "comprehensive" regulatory scheme and the potential significant penalties associated with noncompliance, it can be readily inferred that Defendants and those working at or under their direction closely monitored the Company's marketing, sales, and promotional activities during the Relevant Period.

DEFENDANTS WERE PARTICULARLY MOTIVATED TO INCREASE THE SALES OF HUMIRA DURING THE RELEVANT PERIOD

422. During the Relevant Period, Defendants Gonzalez and Chase collectively received more than $176 million in compensation, which was heavily weighted in stock awards and other

incentive compensation. Defendant Gonzalez earned between $1.5 million and $1.65 million in annual salary, yet he received annual stock awards and other incentive compensation totaling over $116 million during the Relevant Period. Defendant Chase earned between $790,000 and $1,038,773 in annual salary, yet he received nearly $45 million in annual stock awards and other incentive plan compensation during the Relevant Period.

423. AbbVie utilized a Performance Incentive Plan, or "PIP," which rewarded executives for achieving key financial and non-financial goals measured at the Company and individual executive levels.

424. Defendants Gonzalez and Chase were motivated to increase the sales of Humira in order to maximize their compensation because "Humira sales" were one element of a set of financial factors that were evaluated as part of the Company's executives' compensation, which directly impacted their PIP award. Recent Congressional testimony by Gonzalez underscores the direct relationship between Humira sales and executive compensation at the Company.

425. Likewise, the Company was particularly motivated to increase sales of Humira during the Relevant Period because of the pending threat of generic competition.

DEFENDANTS HAVE ENGAGED IN A PATTERN OF WRONGDOING

426. Courts have recognized that "pattern evidence," *i.e.*, evidence that a defendant participated in a pattern of malfeasance over a significant period of time, is probative of scienter. That rule has direct application to the case at bar. Significantly, the DOI Superseding Complaint was not the first time that AbbVie had been accused of providing kickbacks to induce physicians to write prescriptions for its drugs. In October 2018, AbbVie and Abbott settled a whistleblower lawsuit filed in 2009 that claimed those companies had increased prescriptions for their heart medication, Tri Cor, by providing kickbacks to physicians and promoting it for unapproved use.

427. Indeed, the kickback scheme alleged herein is not even the first time that AbbVie has been accused of using illegal means to increase profits generated by sales of Humira.

428. U.S. lawmakers and others have called on the Federal Trade Commission to investigate whether patent-related settlements involving Humira are "pay-for-delay" tactics calculated to hinder generic equivalents from entering the market. "AbbVie is using pay-for-delay deals to keep a cheaper generic off the market and patients are the victims," said David Mitchell, president and co-founder of Patients For Affordable Drugs. "We believe it is illegal and anticompetitive, and we are asking the FTC to step in and protect patients from AbbVie's price hikes."

429. For example, on September 28, 2017, AbbVie issued a press release announcing a global resolution of all intellectual property-related litigations with Amgen regarding Amgen's proposed biosimilar adalimumab product (*i.e.*, generic of Humira). Under the terms of the settlement agreement, AbbVie granted Amgen a non-exclusive license to AbbVie's intellectual property relating to Humira beginning on January 31, 2023 in the United States.

430. Additionally, in July 2018, AbbVie announced that it had reached a patent license agreement with Mylan, a generic developer, over a biosimilar adalimumab. Under the agreement, AbbVie granted Mylan a nonexclusive license to sell its drug in the United States and in other markets outside of Europe. Notably, Mylan's U.S. license will not start until July 2023.

431. AbbVie also engages in a concept known as "patent-thicket" to protect its Humira profits and keep competitors from entering the market with a generic equivalent. While patents provide companies the exclusive right to sell their drug for 20 years, AbbVie has gamed the system to extend these protections well beyond the allotted protection period. To that end, the Company filed applications for additional, overlapping patents to prevent competitors from entering the market.

432. In August 2018, the Initiative for Medicines, Access, and Knowledge ("I-MAK"), a public interest group that seeks to ensure that patents do not obstruct patient access to affordable medicines, issued a report detailing the number of patents that drug makers have attempted to secure for the highest-grossing drugs in the United States. I-MAK called AbbVie "the worst patent offender" in the pharmaceutical landscape for attempting to obtain 247 patents for Humira, while raising the drug's price by 144% since 2012.

433. In March 2019, a class action lawsuit was filed against AbbVie and a group of rival pharmaceutical manufacturers, alleging that the Company colluded to divide the market for AbbVie's blockbuster drug Humira between the United States and Europe, and that AbbVie used a "patent thicket" to maintain an illegal monopoly on Humira. The action seeks damages and injunctive relief for individuals who purchased Humira and for entities that provided reimbursement for some or all of the purchase of Humira in the United States since January 1, 2017. According to the complaint, AbbVie "secured over 100 patents designed solely to insulate Humira from any biosimilar competition in the U.S. for years to come."

434. Since March 2019 at least five other lawsuits have been filed against AbbVie alleging that the Company engaged in anti-competitive behavior by creating a patent thicket to prevent competitors from entering the market with a generic equivalent to Humira. These actions have since been consolidated into the single action of *In re: Humira (Adalimumab) Antitrust Litigation*, 1:19-cv-01873 (N.D. Ill.).

435. AbbVie executives have stated their intention to use patents to deter competition. For example, at the Goldman Sachs Healthcare Conference on June 11, 2014, Defendant Chase stated: "The bulk of that IP strategy, although there's a lot of strategies in there, ***is designed to make it more difficult for a biosimilar to follow behind you and come up with a very, very similar biosimilar***."

DEFENDANTS' VIOLATION OF COMPANY POLICY

436. The Company purports to have a robust ethics and compliance program. In that regard, AbbVie stressed that it "does not tolerate illegal or unethical behavior in any aspect of our business" and that it "emphasizes the importance of ethical and honest conduct, [and] adhering to AbbVie's policies and procedures." AbbVie further emphasized that it "complie[d] with legal, industry and relevant institutions' requirements regarding the interaction of our employees with healthcare professionals and organizations."

THE ABRUPT RESIGNATION OF DEFENDANT CHASE

437. On October 18, 2018, just one month after news of the filing of the DOI Superseding Complaint came to light and caused AbbVie's stock price to fall and investors to incur hundreds of millions of dollars in damages, AbbVie announced that Defendant Chase had abruptly stepped down from his position as CFO of the Company after six years in that role. No explanation for his sudden resignation was provided.

DEMAND FUTILITY ALLEGATIONS

438. Plaintiff brings this action derivatively in the right and for the benefit of AbbVie to redress injuries suffered and to be suffered by AbbVie because of the breaches of fiduciary duty and other wrongs as alleged herein by the Director Defendants.

439. Plaintiff will adequately and fairly represent the interests of AbbVie and its shareholders in enforcing and prosecuting its rights and has retained counsel competent and experienced in derivative litigation.

440. Plaintiff is a current owner of the Company stock and has continuously been an owner of Company stock during all times relevant to the Director Defendants' wrongful course of conduct

alleged herein. Plaintiff understands his obligation to hold stock throughout the duration of this action and is prepared to do so.

441. Because of the facts set forth herein, Plaintiff has not made a demand on the Board of AbbVie to institute this action against the Director Defendants. Such demand would be a futile and useless act because the Board is incapable of making an independent and disinterested decision to institute and vigorously prosecute this action. The AbbVie Board is currently comprised of Defendants Gonzalez, Alpern, Austin, Burnside, Hart, Liddy, Meyer, Rapp, Tilton, Waddell and Roberts. Thus, Plaintiff is required to show that a majority of the Director Defendants cannot exercise independent objective judgment about whether to bring this action or whether to vigorously prosecute this action.

442. The Director Defendants face a substantial likelihood of liability in this action because they caused AbbVie to issue false and misleading statements concerning the information described herein. Because of their advisory, executive, managerial, and directorial positions with AbbVie, the Director Defendants had knowledge of material non-public information regarding the Company and were directly involved in the operations of the Company at the highest levels.

443. The Director-Defendants knew of the falsity of the misleading statements at the time they were made and knew that they had caused the Company to engage in the kickback scheme as it was occurring. HUMIRA is the Company's largest product and is responsible for the majority of the Company's revenue. The prescription of HUMIRA goes to the core operations of AbbVie.

444. The Director Defendants either knew or should have known of the false and misleading statements that were issued on the Company's behalf and took no steps in a good faith effort to prevent or remedy that situation, proximately causing millions of dollars of losses for AbbVie shareholders.

445. The Director Defendants (or at the very least a majority of them) cannot exercise independent objective judgment about whether to bring this action or whether to vigorously prosecute this action. For the reasons that follow, and for reasons detailed elsewhere in this Complaint, Plaintiff has not made (and is excused from making) a pre-filing demand on the Board to initiate this action because making a demand would be a futile and useless act.

446. Any suit by the Board to remedy these wrongs would likely expose the Company to further violations of the securities laws that would result in civil actions being filed; thus, the Board members are hopelessly conflicted in making any supposedly independent determination about whether to sue themselves.

447. The Director Defendants approved and/or permitted the wrongs alleged herein to have occurred and participated in efforts to conceal or disguise those wrongs from the Company's stockholders or recklessly and/or with gross negligence disregarded the wrongs complained of herein and are therefore not disinterested parties.

448. The Director Defendants authorized and/or permitted the Company to make false statements that disseminated directly to the public and made available and distributed to shareholders, authorized and/or permitted the issuance of various false and misleading statements, and are principal beneficiaries of the wrongdoing alleged herein, and thus, could not fairly and fully prosecute such a suit even if they instituted it.

ADDITIONAL FACTS REGARDING DEMAND FUTILITY

Defendant Gonzalez

449. Demand on Defendant Gonzalez is futile. Defendant Gonzalez has served as the Company's CEO and Chairman of the Board since December 2012. The Company also admits that Defendant Gonzalez is a non-independent director. Further, Defendant Gonzalez receives significant

compensation from the Company, including $22,625,243 in the fiscal year ended December 31, 2017. Defendant Gonzalez's insider sales before the scheme was exposed, yielded him over $60.7 million in proceeds. This demonstrates his motive in facilitating and participating in the kickback scheme. As the Company's highest officer, Defendant Gonzalez conducted little oversight of the Company's engagement in the kickback scheme, consciously disregarded his duties to monitor such controls over reporting and engagement in the scheme, and consciously disregarded his duties to protect corporate assets.

450. In addition, Defendant Gonzalez is a defendant in the Securities Class Action. For these reasons, Defendant Gonzalez faces a substantial likelihood of liability and thus demand upon him is futile and, therefore, excused.

451. Defendant Gonzalez served as Abbott's executive vice president of the pharmaceutical products group from July 2010 to December 2012, and was responsible for Abbott's worldwide pharmaceutical business, including commercial operations, research and development, and manufacturing. He also served as president, Abbott Ventures Inc., Abbott's medical technology investment arm, from 2009 to 2011. Gonzalez joined Abbott in 1977 and held various management positions before briefly retiring in 2007, including: Abbott's president and chief operating officer; president, chief operating officer of Abbott's Medical Products Group; senior vice president and president of Abbott's former Hospital Products Division; vice president and president of Abbott's Health Systems Division; and divisional vice president and general manager for Abbott's Diagnostics Operations in the United States and Canada.

452. Further, Defendant Gonzalez was an executive of Abbott when Abbott pled guilty and agreed to pay $1.5 billion to resolve its criminal and civil liability arising from the company's

unlawful promotion of the prescription drug Depakote for uses not approved as safe and effective by the Food and Drug Administration ("FDA").

Defendant Alpern

453. Demand on Defendant Alpern is futile. Defendant Alpern has served as a Company director since 2013 and serves as a member of the Nominations and Governance Committee and the Public Policy Committee. Defendant Alpern receives compensation from the Company, including $335,929 in the fiscal year ended December 31, 2017. Defendant Alpern conducted little oversight of the Company's engagement in the kickback scheme. Defendant Alpern signed the 2014-2017 10-Ks that contained the false and misleading statements referenced herein.

454. Defendant Alpern is a director of Abbott, the parent company of AbbVie.

455. Defendant Alpern was a director of Abbott when Abbott pled guilty and agreed to pay $1.5 billion to resolve its criminal and civil liability arising from the company's unlawful promotion of the prescription drug Depakote for uses not approved as safe and effective by the FDA.

Defendant Austin

456. Demand on Defendant Austin is futile. Defendant Austin has served as a Company director since 2013 and serves as Chairperson of the Audit Committee and a member of the Compensation Committee. Defendant Austin receives compensation from the Company, including $320,300 in the fiscal year ended December 31, 2017. Defendant Austin conducted little oversight of the Company's engagement in the kickback scheme. Defendant Austin signed the 2014-2017 10-Ks that contained the false and misleading statements referenced herein.

457. Defendant Austin is a director of Abbott Laboratories, the parent company of AbbVie.

458. Defendant Austin was a director of Abbott when Abbott pled guilty and agreed to pay $1.5 billion to resolve its criminal and civil liability arising from the company's unlawful promotion of the prescription drug Depakote for uses not approved as safe and effective by the FDA.

Defendant Burnside

459. Demand on Defendant Burnside is futile. Defendant Burnside has served as a Company director since 2013 and serves as a member of the Audit Committee and Nominations and Governance Committee. Defendant Burnside receives compensation from the Company, including $320,981 in the fiscal year ended December 31, 2017. Defendant Burnside conducted little oversight of the Company's engagement in the kickback scheme. Defendant Burnside signed the 2014-2017 10-Ks that contained the false and misleading statements referenced herein.

Defendant Liddy

460. Demand on Defendant Liddy is futile. Defendant Liddy has served as a Company director since 2013 and serves as Chairperson of the Compensation Committee and as a member of the Public Policy Committee. Defendant Liddy receives compensation from the Company, including $309,981 in the fiscal year ended December 31, 2017. Defendant Libby conducted little oversight of the Company's engagement in the kickback scheme. Defendant Liddy signed the 2014-2017 10-Ks that contained false and misleading statements referenced herein.

461. Defendant Liddy is a director of Abbott Laboratories, the parent company of AbbVie.

462. Defendant Liddy was a director of Abbott when Abbott pled guilty and agreed to pay $1.5 billion to resolve its criminal and civil liability arising from the company's unlawful promotion of the prescription drug Depakote for uses not approved as safe and effective by the FDA.

Defendant Rapp

463. Demand on Defendant Rapp is futile. Defendant Rapp has served as a Company director since 2013 and serves as Chairperson of the Public Policy Committee and as a member of the Audit Committee. Defendant Rapp receives compensation from the Company, including $342,025 in the fiscal year ended December 31, 2017. Defendant Rapp conducted little oversight of the Company's engagement in the kickback scheme. Defendant Rapp signed the 2014-2017 10-Ks that contained the false and misleading statements in the 2014-2017 10-Ks referenced herein.

Defendant Tilton

464. Demand on Defendant Tilton is futile. Defendant Tilton has served as a Company director since 2013, and serves as Lead Director, Chairperson of the Nominations and Governance Committee, and as a member of the Compensation Committee. Defendant Tilton receives compensation from the Company, including $359,981 in the fiscal year ended December 31, 2017. Defendant Tilton conducted little oversight of the Company's engagement in the kickback scheme. Defendant Tilton signed the 2014-2017 10-Ks that contained the false and misleading statements referenced herein.

465. Defendant Tilton is a director of Abbott Laboratories, the parent company of AbbVie.

466. Defendant Tilton was a director of Abbott when Abbott pled guilty and agreed to pay $1.5 billion to resolve its criminal and civil liability arising from the company's unlawful promotion of the prescription drug Depakote for uses not approved as safe and effective by the FDA.

Defendant Waddell

467. Demand on Defendant Waddell is futile. Defendant Waddell has served as a Company director since 2013 and serves as a member of the Audit Committee and the Compensation Committee. Defendant Waddell receives compensation from the Company, including $320,981 in the fiscal year ended December 31, 2017. Defendant Waddell conducted little oversight of the

Company's engagement in the kickback scheme. Defendant Waddell signed the 2014-2017 10-Ks that contained the false and misleading statements referenced herein.

Defendant Hart

468. Demand on Defendant Hart is futile. Defendant Hart has served as a Company director since 2013 and serves as a member of the Nominations and Governance Committee. Defendant Hart receives compensation from the Company, including $314,981 in the fiscal year ended December 31, 2017. Defendant Hart conducted little oversight of the Company's engagement in the kickback scheme. Defendant Hart signed 2016 and 2017 10-Ks that contained the false and misleading statements referenced herein.

Defendant Meyer

469. Demand on Defendant Meyer is futile. Defendant Meyer has served as a Company director since 2013 and serves as a member of the Audit Committee and the Public Policy Committee. Defendant Meyer receives compensation from the Company, including $274,731 in the fiscal year ended December 31, 2017. Defendant Meyer conducted little oversight of the Company's engagement in the kickback scheme. Defendant Meyer signed the 2017 10-K that contained the false and misleading statements referenced herein.

Defendants Alpern, Austin, Liddy, Tilton and Gonzalez

470. In 2012, Defendants Alpern, Austin, Liddy and Tilton were all members of the Abbott board of directors and Gonzalez was Abbott's Executive Vice President of the pharmaceutical products when Abbott pled guilty and agreed to pay $1.5 billion to resolve its criminal and civil liability arising from the company's unlawful promotion of the prescription drug Depakote for uses not approved as safe and effective by the Food and Drug Administration ("FDA"). *See* Exhibit B for Agreed Statement of Facts in the criminal action entitled *United States v. Abbott Laboratories*,

Criminal No. 12cr26 (W.D. Virginia); *see also* Exhibit C for Settlement Agreement in the criminal action entitled *United States v. Abbott Laboratories*, Criminal No. 12cr26 (W.D. Virginia).

471. While these defendants were members of the board of Abbott and Gonzalez was a high ranking officer, Abbott has agreed to pay $800 million to the federal government ($560,851,357) and the states ($239,148,643) that opted to participate in the agreement to resolve claims that its unlawful marketing and illegal remuneration practices caused false claims to be submitted to government health care programs such as Medicare, Medicaid, TRICARE and to the Federal Employees Health Benefit Program, the Department of Veterans' Affairs and the Department of Labor's Office of Workers' Compensation Programs.

472. The civil settlement addressed broader allegations by the United States that from 1998 through 2008, Abbott unlawfully promoted Depakote for unapproved uses, including behavioral disturbances in dementia patients, psychiatric conditions in children and adolescents, schizophrenia, depression, anxiety, conduct disorders, obsessive-compulsive disorder, post-traumatic stress disorder, alcohol and drug withdrawal, attention deficit disorder and autism. Some of these unapproved uses were not medically accepted indications for which the United States and state Medicaid programs provided coverage for Depakote. The United States contended that this promotion included, in part, making false and misleading statements about the safety, efficacy, dosing and cost-effectiveness of Depakote for some of these unapproved uses, and claiming use of Depakote to control behavioral disturbances in dementia patients would help nursing homes avoid the administrative burdens and costs of complying with OBRA regulatory restrictions applicable to antipsychotics.

473. The civil settlement also covered allegations that Abbott offered and paid illegal remuneration to health care professionals and long term care pharmacy providers to induce them to promote and/or prescribe Depakote and to improperly and unduly influence the content of company

sponsored Continuing Medical Education programs, in violation of the Federal Anti-Kickback Statute.

474. Defendants Alpern, Austin, Liddy and Tilton were all members of the Abbott board of directors and Gonzalez was Abbott's Executive Vice President of the pharmaceutical products when Abbott pled guilty and agreed to pay $1.5 billion to resolve its criminal and civil liability arising from the company's unlawful promotion of the prescription drug Depakote for uses not approved as safe and effective by the FDA. These same officers and directors are members of the AbbVie Board during the Company's illegal kickback scheme through which it provided physicians with goods and services, including cash, in return for prescribing Humira. AbbVie's wrongdoing was initially challenged by a whistleblower and then by the California Department of Insurance ("CDI"), which, following a seven-month investigation, stated, "***We believe there is strong evidence that fraud was committed" and described the wrongdoing as the "largest health care fraud case***" in CDI history.

475. Humira is the Company's blockbuster drug, accounting for two-thirds of AbbVie's overall sales. This drug is critical to AbbVie's operations and implicates "mission critical regulatory issues" concerning the adequacy of internal controls regarding illegal kickbacks.

FIRST CAUSE OF ACTION

(Against The Director Defendants For Breach Of Fiduciary Duty)

476. Plaintiff incorporates by reference and re-alleges each allegation contained above, as though fully set forth herein.

477. The Director Defendants owed and owe AbbVie fiduciary obligations. By reason of their fiduciary relationships, the Director Defendants owed and owe AbbVie the highest obligation of good faith, fair dealing, loyalty and due care.

478. The Director Defendants, and each of them, violated and breached their fiduciary duties of care, loyalty, reasonable inquiry, oversight, good faith and supervision.

479. The Director Defendants had actual or constructive knowledge that they had caused the Company to improperly misrepresent the business prospects of the Company. These actions could not have been a good faith exercise of prudent business judgment to protect and promote the Company's corporate interests.

480. As a direct and proximate result of the Director Defendants' failure to perform their fiduciary obligations, AbbVie has sustained significant and actual damages. As a result of the misconduct alleged herein, the Director Defendants are liable to the Company.

SECOND CAUSE OF ACTION

(Against Defendants For Unjust Enrichment)

481. Plaintiff incorporates by reference and re-alleges each and every allegation set forth above, as though fully set forth herein.

482. By their wrongful acts and omissions, Defendants were unjustly enriched at the expense of and to the detriment of AbbVie in the form of salaries, bonuses, and other forms of compensation.

483. Plaintiff, as a shareholder and representative of AbbVie, seeks restitution from Defendants, and each of them, and seeks an order of this Court disgorging all profits, benefits and other compensation obtained by these Defendants, and each of them, from their wrongful conduct and fiduciary breaches.

484. Plaintiff, on behalf of AbbVie, has no adequate remedy at law.

THIRD CAUSE OF ACTION

(Against Defendants For Abuse of Control)

485. Plaintiff incorporates by reference and re-alleges each and every allegation set forth above, as though fully set forth herein.

486. Defendants' misconduct alleged herein constituted an abuse of their ability to control and influence the Company, for which they are legally responsible.

487. As a direct and proximate result of Defendants' abuse of control, the Company has sustained significant damages. As a direct and proximate result of Defendants' breaches of their fiduciary obligations of candor, good faith, and loyalty, the Company has sustained and continues to sustain significant damages.

488. As a result of the misconduct alleged herein, Defendants are liable to the Company.

FOURTH CAUSE OF ACTION

(Against Defendants For Waste of Corporate Assets)

489. Plaintiff incorporates by reference and re-alleges each and every allegation set forth above, as though fully set forth herein.

490. As a result of the foregoing, and by failing to properly consider the interests of the Company and its public shareholders, Defendants have caused the Company to waste valuable corporate assets by failing to disclose (i) the Company had a material weakness in its internal control over financial reporting; (ii) the Company's disclosure controls and procedures were not effective; and (iii) as a result of the foregoing, the Company's public statements were materially false and misleading at all relevant times.

491. As a result of the waste of corporate assets, Defendants are each liable to the Company.

FIFTH CAUSE OF ACTION

(Against Defendants for Violations of Section 10(b) of the Exchange Act and SEC Rule 10(b)-5)

492. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

493. During the Relevant Period, the Director Defendants disseminated or approved public statements that failed to disclose (i) AbbVie's strategy to maintain and increase the sales growth of its blockbuster drug, Humira, relied in part upon systematic illegal kickbacks and unlawful sales and marketing tactics; (ii) such practices would foreseeably lead to heightened scrutiny by state governments and agencies; and (iii) as a result, the Company's public statements were materially false and misleading at all relevant times. Thus, the price of the Company's shares was artificially inflated due to the deception of the Director Defendants. Despite this artificial inflation in the price of the Company's shares, the Director Defendants caused and/or allowed the Company to repurchase many millions of shares of Company stock, thereby causing financial harm to the Company.

494. On October 20, 2014, the Board authorized the purchase of up to $5.0 billion of its common stock.

495. On February 16, 2017, the Board authorized a $5.0 billion increase to the Company's existing stock repurchase program.

496. On February 15, 2018, the Board authorized a new $10.0 billion stock repurchase program, which superseded the Company's previous stock repurchase program.

497. As alleged herein, Director Defendants acted with scienter in that they knew that the public documents and statements issued or disseminated in the name of the Company were materially false and misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the

federal securities laws. As set forth elsewhere herein in detail, Director Defendants, by virtue of their receipt of information reflecting the true facts regarding AbbVie, their control over, and/or receipt and/or modification of the Company's allegedly materially misleading statements and/or their associations with the Company which made them privy to confidential proprietary information concerning AbbVie, participated in the fraudulent scheme alleged herein.

498. Director Defendants knew and/or recklessly disregarded the false and misleading nature of the information which they caused to be disseminated to the investing public. The fraudulent scheme described herein could not have been perpetrated during the Relevant Period without the knowledge and complicity or, at least, the reckless disregard of the personnel at the highest levels of the Company, including the Director Defendants.

499. Certain of the Defendants also engaged in insider selling while in possession of non-public information in violation of the securities laws.

500. The Director Defendants were each members of AbbVie's Board during the aforesaid time period. Based on their roles at AbbVie, each of the Director Defendants would have been involved with, or knowledgeable about, the wrongdoing alleged herein.

501. At a minimum, the Director Defendants failed to review or check information that they had a duty to monitor or ignored obvious signs that their statements were materially false and misleading or contained material omissions. Given the nature and extent of the problems at AbbVie, the Director Defendants knew and/or recklessly disregarded the extent and scope of their statements during the Relevant Period.

502. Likewise, certain Director Defendants, by virtue of their high-level positions with the Company, directly participated in the management of the Company, were directly involved in the day-to-day operations of the Company at the highest levels, and were privy to confidential

proprietary information concerning the Company and its business, operations, financial statements, and financial condition, as alleged herein. The Director Defendants had the ultimate authority over and were involved in drafting, producing, reviewing and/or disseminating the false and misleading statements and information alleged herein, were aware, or recklessly disregarded, that the false and misleading statements regarding the Company were being issued, and approved or ratified these statements, in violation of the federal securities laws.

503. As such Director Defendants caused the Company to violate section 10(b) of the Exchange Act and SEC Rule 10b-5 in that they:

(a) employed devices, schemes, and artifices to defraud; and

(b) made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

SIXTH CAUSE OF ACTION

(Derivative Claim For Violations Of Section 20(a) Of The Exchange Act Against Defendant Gonzalez)

504. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

505. This Count is asserted on behalf of the Company against Defendant Gonzalez for violations of Section 20(a) of the Exchange Act, 15 U.S.C. § 78t(a).

506. During his tenure as an executive officer and/or Chairman of the Board, Defendant Gonzalez was a controlling person of all officers of the Company within the meaning of Section 20(a) of the Exchange Act. By reason of his control, Defendant Gonzalez had the power and authority to direct the management and activities of the other Company officers, to hire and fire the other Company officers at whim, and to cause the other Company officers to engage in the

wrongful conduct complained of herein. Defendant Gonzalez was able to and did control, directly or indirectly, the content of the public statements made by all other Company officers during the Relevant Period, including the materially misleading financial statements, thereby causing the dissemination of the false and misleading statements and omissions of material facts as alleged herein.

507. In his capacity as the senior executive, and Chairman of the Board of AbbVie, Defendant Gonzalez had direct involvement in and oversight over the day-to-day operations of the Company officers and the Company's employees, who would not act unless Defendant Gonzalez agreed with his course of conduct.

508. As a result of the foregoing, Defendant Gonzalez, individually, was a controlling person of the other Company officers within the meaning of Section 20(a) of the Exchange Act.

509. As a direct and proximate result of Defendant Gonzalez's conduct, the Company suffered damages in connection with its purchase of AbbVie common stock at materially inflated prices.

SEVENTH CAUSE OF ACTION

(Against The Director Defendants For Violations Of Section 14(a) Of The Exchange Act And SEC Rule 14a-9)

510. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

511. SEC Rule 14a-9, promulgated pursuant to section 14(a) of the Exchange Act, provides that no proxy statement shall contain "any statement which, at the time and in the light of the circumstances under which it is made, is false or misleading with respect to any material fact, or which omits to state any material fact necessary in order to make the statements therein not false or misleading." 17 C.F.R. § 240.14a-9.

512. The 2016 Proxy Statement failed to disclose that: (a) the Company engaged in a kickback scheme, leading to increased scrutiny from governmental agencies; and (b) the Company failed to maintain internal controls.

513. The 2016 Proxy Statement stated that the Company's executive officers submit annually certifications related to their compliance with the Code of Conduct and that the Company requires mandatory training on its code of conduct. In addition, the 2016 Proxy Statement referenced the Governance Guidelines. The 2016 Proxy Statement was false and misleading because the Company's Code of Conduct and Governance Guidelines were not followed as a result of the misconduct detailed herein.

514. The Director Defendants also caused the 2016 Proxy Statement to be false and misleading regarding the executive compensation. For example, the 2016 Proxy Statement purported to employ a "pay-for-performance process" while failing to disclose that the Company's financial prospects were misrepresented as a result of false and misleading statements.

515. The Director Defendants should have known that by misrepresenting or failing to disclose the foregoing material facts stated herein, the statements contained in the 2016 Proxy Statement were materially false and misleading. The misrepresentations and omissions were material to Plaintiff in voting on the matters set forth for shareholder determination in the 2016 Proxy Statement, including but not limited to the approval of the PIP.

516. The solicitation to approve the PIP was successful and the shareholders voted to approve the PIP.

517. In order to profit using the PIP, Defendants needed to show net earnings from their illegal kickback scheme and unlawful sales and marketing practices in order to generate the payments.

518. As set forth herein, Defendants caused the financial statements of the Company to be false and misleading as they used the unsustainable financial results generated by their illegal kickback scheme and unlawful sales and marketing practices to inflate the earnings and revenues of the Company. They also caused the price of the Company's stock to be artificially inflated.

519. Upon information and belief, Senior Executive Officers received payments under the PIP, during the same time they were making insider sales of Company stock. Defendants caused the financial statements of the Company to be false and misleading because of their involvement in the illegal kickback scheme and unlawful sales and marketing practices and boosted the Company's Consolidated Net Earnings in order to benefit from the PIP.

520. This misconduct by the Defendants in connection with the 2016 Proxy Statement continued to produce ill-gotten benefits in 2017, 2018 and thereafter. Upon information and belief, Senior Executive Officers continued to receive payments under the PIP which they otherwise were not entitled to received, had the Company's Consolidated Net Earnings not been illegally increased by the kickback scheme.

521. Accordingly, Defendants must obtain the disgorgement of all ill-gotten gains received by Senior Executive Officers and to pay damages for violation of the federal securities laws.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff pray for relief and judgment as follows:

A. Declaring that Plaintiff may maintain this action on behalf of the Company and that Plaintiff is an adequate representative of the Company;

B. Against Defendants in favor of the Company for the amount of damages sustained by the Company as a result of Defendants' breaches of fiduciary duties, unjust enrichment, abuse of control, and waste of corporate assets and for disgorgement of all ill-gotten gains received by Defendants and Senior Executive Officers;

C. Directing Defendants to take all necessary actions to reform and improve the Company's corporate governance, risk management, and internal operating procedures to comply with applicable laws and to protect the Company and its stockholders from a repeat of the rampant wrongful conduct described herein;

D. Awarding to Plaintiff the costs and disbursements of the action, including reasonable attorney's fees, accountants' and experts' fees, costs, and expenses; and

E. Granting such other and further relief as the Court deems just and proper.

JURY TRIAL DEMANDED

Plaintiff hereby demands a trial by jury by all issues so triable.

DATED: May 7, 2020

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